

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division**

OUTSOURCING FACILITIES
ASSOCIATION, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, et al.,

Defendants.

Civil Action No. 4:24-cv-00953-P

**Appendix in Support of Plaintiffs' Motion for a
Temporary Restraining Order and Preliminary Injunction**

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Certificate of Service

I hereby certify that a true and accurate copy of the foregoing document was filed electronically (via CM/ECF) on October 8, 2024, and that I caused a copy of the foregoing, and all accompanying papers, to be served via process server and via U.S. mail on the following:

United States Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, Maryland 20903

Dr. Robert M. Califf
10903 New Hampshire Ave.
Silver Spring, Maryland 20903

Dated: October 8, 2024

/s/ Ty Doyle

TY DOYLE (Texas Bar No. 24072075)
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Attorney for Plaintiffs

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division**

OUTSOURCING FACILITIES
ASSOCIATION; NORTH AMERICAN
CUSTOM LABORATORIES, LLC D/B/A
FARMAKEIO CUSTOM COMPOUNDING,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION; and DR. ROBERT M.
CALIFF, in his official capacity as
Commissioner of Food and Drugs,

10903 New Hampshire Ave., Silver Spring,
Maryland 20903

Defendants.

Civil Action No. 4:24-cv-00953-P

Declaration of Dan DeNeui

Pursuant to 28 U.S.C. § 1746, I, Dan DeNeui, declare as follows:

1. I am the Chief Executive Officer and Managing Partner of North American Custom Laboratories, LLC d/b/a FarmaKeio Custom Compounding (“FarmaKeio”). I submit this Declaration in support of Plaintiffs’ motion for a temporary restraining order and preliminary injunction. I have personal knowledge of the facts stated herein.
2. FarmaKeio is a Texas limited liability company headquartered in Southlake, Texas.
3. FarmaKeio owns and operates a compounding pharmacy in Richardson, Texas, that is regulated under Section 503A of the Food, Drug, and Cosmetics Act.
4. FarmaKeio’s compounded prescriptions are prepared in a state-of-the-art facility designed to ensure the highest level of safety, potency, and efficacy.

5. FarmaKeio provides custom compounded prescriptions for a variety of health needs including weight loss, thyroid and adrenal support, hormone therapy, autoimmune/naltrexone, cognitive function, sleep, sexual health, hair loss, gut health, and energy.

Patients Turn to Compounding Pharmacies To Fill Tirzepatide Prescriptions

6. Tirzepatide is the active ingredient of FDA-approved prescription drugs that treat type-2 diabetes and obesity. Tirzepatide is administered via injection and sold under the brand names Mounjaro for diabetes treatment and Zepbound for weight loss. Tirzepatide has been proven effective and is in exceptionally high demand.

7. When the FDA listed Tirzepatide on the Section 506E shortage list in December 2022 (“Drug Shortage List”), compounding pharmacies like FarmaKeio began producing Tirzepatide to satisfy demand and patient needs with compounded version of the drug.

8. As part of my role at FarmaKeio, I routinely evaluate market conditions for the products we provide patients. Demand for compounded Tirzepatide has remained at exceptionally high levels through the month of September 2024, right up to the time of the FDA’s announcement that Tirzepatide is no longer in shortage.

9. Patients and medical providers report that compounded versions of Tirzepatide are generally as effective as Zepbound and Mounjaro.

10. Patients and medical providers have also turned to compounding pharmacies for Tirzepatide prescriptions because compounding pharmacies have provided doses of Tirzepatide at substantially lower costs, such as one-half or even one-quarter the cost of brand-name alternatives.

FarmaKeio's Tirzepatide Compounding Business

11. Until October 2, 2024, Tirzepatide was listed on the FDA's Drug Shortage List. Relying on that listing, FarmaKeio compounded Tirzepatide to ensure that patients would have access to necessary medical care.

12. FarmaKeio began compounding Tirzepatide in January 2023.

13. FarmaKeio compounds Tirzepatide at its facility in Richardson, Texas.

14. Thirty employees work at this FarmaKeio facility.

15. FarmaKeio compounded approximately 18,410mL of Tirzepatide in September 2024, which (given the varied weekly dosing of Tirzepatide) supplied approximately 6,268 patients.

FDA Abruptly Removes Tirzepatide from the Drug Shortage List

16. On October 2, 2024, the FDA removed Tirzepatide from the Drug Shortage List (the "Delisting Action").

17. FDA provided no notice of this decision before it took legal effect. Market participants did not know before that moment that their ongoing compounding activities would become unlawful. FDA provided no opportunity for public comment on whether Tirzepatide remains subject to a shortage as defined by statute.

18. Patients continue to report shortages of Tirzepatide.

19. The FDA's action restricts FarmaKeio's ability to continue compounding Tirzepatide—in particular, drug products that are essentially copies of commercially available Tirzepatide. With Tirzepatide removed from the Drug Shortage List, FarmaKeio will be unable to continue accepting prescriptions for Tirzepatide and filling them with compounded Tirzepatide.

FarmaKeio would continue accepting prescriptions and filling them with compounded Tirzepatide but for FDA's action.

20. If the FDA's decision to delist Tirzepatide from the Drug Shortage List remains in effect, FarmaKeio will be forced to permanently cease its Tirzepatide compounding business.

21. FarmaKeio will suffer approximately \$1,750,000-\$2,000,000 in lost revenue per month as a consequence of the FDA's Delisting Action.

22. The FDA's Delisting Action, if it remains in effect, will cause FarmaKeio to lay off 6-9 employees.

23. If the FDA's Delisting Action remains in effect, the patients that FarmaKeio currently serves will be unable to get their Tirzepatide prescriptions filled by FarmaKeio.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on the 8th day of October, 2024.

Signed by:
Dan DeNeui
4B77FAE31A4A414...

Dan DeNeui

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OUTSOURCING FACILITIES
ASSOCIATION; NORTH AMERICAN
CUSTOM LABORATORIES, LLC D/B/A
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10903 New Hampshire Ave., Silver Spring,
Maryland 20903

Defendants.

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Declaration of Lee Rosebush

Pursuant to 28 U.S.C. § 1746, I, Lee Rosebush, declare as follows:

1. I am the Chairman of Outsourcing Facilities Association and I have personal knowledge of the facts stated herein.
2. Outsourcing Facilities Association (OFA) is the trade association representing FDA-registered 503B outsourcing facilities who focus on providing patients and healthcare providers with safe and effective compounded medications. Every OFA member is an outsourcing facility or affiliate that operates under Section 503B of the Federal Food, Drug, and Cosmetic Act (“FDCA”). OFA members work with patients, healthcare providers, and facilities on a daily basis to ensure the specific needs, of both providers and patients, for compounded medications are satisfied. OFA will continue to work with industry, governmental agencies, and healthcare

providers to educate and advocate for outsourcing facilities and the critical need to ensure that patients and providers have access to the medications they need.

3. As the Chairman of OFA, I run the day-to-day operations of the largest trade association for FDA registered 503B outsourcing facilities.

4. As part of my role at OFA, I regularly correspond and confer with OFA members about their operations and have in-depth personal knowledge about how outsourcing facilities are run, produce products, and satisfy legal standards. I also routinely review a wide range of sources to evaluate supply and demand for drugs like Tirzepatide, which is the active ingredient of FDA-approved prescription drugs that treat type-2 diabetes and obesity. Tirzepatide is administered via injection and sold under the brand names Mounjaro for diabetes treatment and Zepbound for weight loss. Tirzepatide has been proven effective and is in exceptionally high demand.

5. Additionally, in my role at OFA, I interact from time to time with representatives of the Food and Drug Administration (“FDA”), including on issues of drug shortages. I understand that FDA employees monitor the same sources of information that I do and must be aware of the information reported in those sources. I have found these sources to provide reliable information on drug availability, among other things. If in fact FDA officials and employees are not monitoring publicly available sources of information about drug shortages, that would be equivalent to regulatory malpractice.

6. The sources cited below are sources I reviewed in evaluating the public record on whether the shortage of Tirzepatide persists and whether that shortage will be exacerbated when patients are unable to access Tirzepatide from compounding pharmacies.

Compounding Pharmacies Fill Many Tirzepatide Prescriptions

7. Compounding under Sections 503A and 503B serves vital national interests, especially in the case of drug shortages. When a drug is on the drug shortage list, compounding pharmacies operating under Section 503A may compound forms of the drug that are essential copies of FDA-approved forms of the drug, which is otherwise generally prohibited. When a drug is on the drug shortage list, outsourcing facilities operating under Section 503B may compound forms of the drug (including essential copies) that are otherwise generally unlawful to produce, except in narrow circumstances that do not apply to Tirzepatide.

8. The listing on FDA's drug shortage list enabled pharmacies and outsourcing facilities to satisfy demand and patient needs through compounding, including of drugs that are essentially copies of FDA-approved versions of Tirzepatide.

9. When the FDA listed Tirzepatide on the Section 506E shortage list in December 2022, compounding pharmacies began producing Tirzepatide to satisfy demand and patient needs with compounded version of the drug. I conferred with numerous OFA members and learned that they devoted manufacturing lines and substantial resources to filling the nationwide Tirzepatide shortage.

10. Compounding activities by outsourcing facilities require significant investment and lead time before facilities can achieve profitability. Facilities must allocate manufacturing lines to compounding a given drug, which would otherwise be available for other product production. Facilities must also spend money on research, development, and compliance, as well as ingredients. Generally speaking, it takes hundreds of thousands of dollars and approximately 6-9 months of lead time for an outsourcing facility to begin compounding and distributing a drug like Tirzepatide. Profitability is achieved sometime after that.

11. Patients report that compounded versions of Tirzepatide are generally as effective as Zepbound or Mounjaro. Exhibit 1 is a true and correct copy of a Reddit¹ thread where patients discuss their experiences with compounded Tirzepatide compared to Zepbound. These reports comport with my personal knowledge of the efficacy of compounded forms of Tirzepatide.

12. NBC News reported that doctors are “embracing compounded versions of popular weight loss drugs.” Exhibit 2 is a true and correct copy of the NBC article.

13. Patients report that they will continue using compounded versions of Tirzepatide for as long as possible because the cost is substantially lower. Exhibit 3 is a true and correct copy of a Reddit thread where patients discuss the lower costs of compounded Tirzepatide.

14. RO, a telehealth care company, reported on September 29, 2024 that compounded Tirzepatide costs about one-third of the price of Zepbound or Mounjaro. Exhibit 4 is a true and correct cope of the RO article, *How much does tirzepatide cost with and without insurance?*

15. CBS News reported that some patients are finding compounded Tirzepatide to be one-third the cost of Zepbound. Exhibit 5 is a true and correct copy of the CBS News article.

16. Compounding pharmacies fill prescriptions for millions of patients. Exhibit 6 is a true and correct copy of a CBS News article reporting “that several large compounding pharmacies...are provisioning up to 2 million American patients with regular doses of semaglutide, the scientific name for Novo Nordisk's Wegovy, Ozempic and Rybelsus formulations, or tirzepatide, the active ingredient in Eli Lilly’s Zepbound and Mounjaro.”

¹ Reddit is a prominent social news website that is home to thousands of communities, where people around the world post, vote, and comment in forums organized around their interests.

17. KFF Health News republished the CBS News article reporting that 2 million patients obtain their prescription from compounding pharmacies. Exhibit 7 is a true and correct copy of the KFF Health News article.

18. The Washington Post reported that “[u]p to 30 percent of the market, by some estimates, is made up of copycat versions from compounding pharmacies.” Exhibit 8 is a true and correct copy of the Washington Post article reporting this.

19. Because many patients fill their prescriptions through compounding pharmacies, the shortages will be exacerbated when patients are no longer able to fill prescriptions from compounding pharmacies. Exhibit 9 is a true and correct copy of a Reddit thread where patients discuss this exact concern.

Shortages Persist Despite Access to Compounded Tirzepatide

20. From news sources to trade publications and online forums to social media posts, there has been widespread reporting on patients continued inability to fill prescriptions for Tirzepatide, despite assertions from the drug manufacturers about availability. My conversations and correspondence with OFA members confirms that these reports are accurate: even with compounded forms of Tirzepatide available, not all market demand has been satisfied since December 2022.

21. Because the market demand for Tirzepatide has been exceptionally high, patients have turned to compounding pharmacies to fill prescription orders that could not be filled otherwise. Even with compounding pharmacies and outsourcing facilities providing millions of Tirzepatide doses per month, patients around the country have still struggled to get their prescriptions timely filled. Some patients have been forced to wait days or weeks to have their Tirzepatide prescriptions filled.

22. BioPharma Dive, which is a leading industry publication on biotech and pharma, reported that even though Zepbound and Mounjaro are listed as available that does not mean, according to Lilly's CEO David Ricks, that "any pharmacy, or certainly every pharmacy, has all 12 dosage forms sitting on their shelves." Exhibit 10 is a true and correct copy of BioPharma Dive's article on supply shortages.

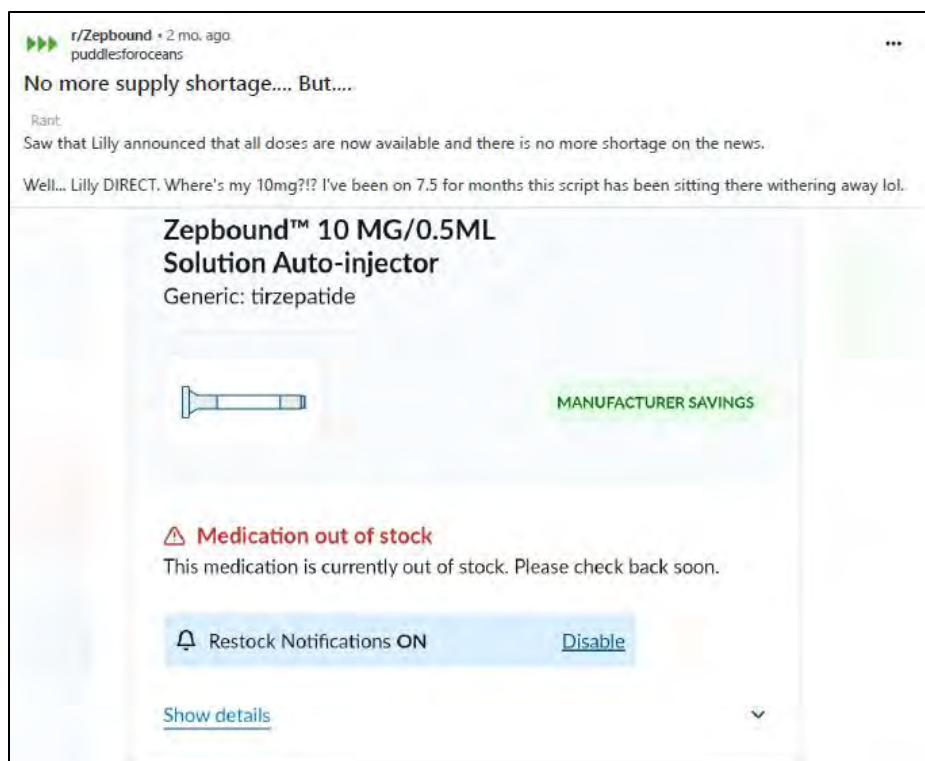
23. With the tagline "define 'available,'" Politico reported that while all doses of Eli Lilly's GLP-1 drug were listed as "available," pharmacists were still facing obstacles in ordering Mounjaro and Zepbound. Exhibit 11 is a true and correct copy of Politico's article on supply shortages.

24. In September 2024, NPR reported that "[d]rugmakers say obesity medicine shortages are easing, but patients struggle to fill prescriptions." Exhibit 12 is a true and correct copy of NPR's article on supply shortages.

25. In September 2024, RO reported that Eli Lilly, the manufacturer of FDA-approved forms of Tirzepatide, "expects demand to continue to outpace supply throughout 2024." Exhibit 13 is a true and correct copy of RO's September 10, 2024 article on supply shortages.

26. In October 2024, RO reported that "[d]rug shortages continue to be a major hurdle preventing tens of millions of patients from starting or continuing their GLP-1 treatment." Exhibit 14 is a true and correct copy of RO's October 3, 2024 article on supply shortages.

27. In reviewing an online forum on Reddit where patients have been discussing where to find Tirzepatide given the enduring shortages, I learned that patients continue to report difficulty getting prescriptions for Tirzepatide filled, despite statements from drug manufacturers that the shortage has ceased to exist. Exhibit 15 is a true and correct copy of the Reddit thread discussing supply shortages for Tirzepatide.



28. Demand for compounded Tirzepatide has remained at exceptionally high levels through the month of September 2024, right up to the time of the FDA's announcement that Tirzepatide is no longer in shortage.

FDA's Knew the Shortage Persisted Yet Delisted Tirzepatide Without Notice and Comment

29. Various industry participants have recently presented FDA information showing extremely high demand for Tirzepatide, inability of its manufacturer to keep up, scarcity in various regions and at the national level, and delays in filling prescriptions.

30. I have personal knowledge of specific submissions of information directly to FDA showing that a shortage for Tirzepatide exists: this information must be included on any fairly compiled administrative record in this case. I am aware that FDA received information from at least two major national telehealth companies, which collect information from customers about ability to obtain drugs. One reported to FDA on September 10, 2024, that it received 500 to 700 *daily* reports of patients reporting to *just that company* an inability to obtain a branded version of

Tirzepatide. Another sent FDA periodic updates to FDA, including thousands of shortage reports indicating inability of patients to obtain Mounjaro and Zepbound.

31. FDA also received reports from outsourcing pharmacies (including OFA members) of voluminous Tirzepatide compounding meeting high demand. I personally reported to FDA that OFA members were seeing very high demand that the supply side of the market—even with drug compounding—was not adequately meeting.

32. Despite the evidence, FDA abruptly declared on its website on October 2, 2024, that “the shortage of tirzepatide injection...has been resolved” and removed Tirzepatide from the shortage list.

33. FDA provided no notice of this decision before it took legal effect. FDA provided no opportunity for public comment on whether Tirzepatide remains subject to a shortage as defined by statute.

34. Market participants did not know before that moment that their ongoing compounding activities would immediately become unlawful.

35. The day before FDA removed Tirzepatide from the shortage list, a massive port-worker strike commenced from Texas all the way to Maine, and everywhere in between. Exhibit 16 is a true and correct copy of an article on the port strike. I personally sent an article about the port strike’s impact on the availability of Tirzepatide to a representative of FDA involved in the decision to delist Tirzepatide, who responded: “yes we are aware of this article.” Exhibit 17 is a true and correct copy of the FDA representative’s email response.

36. I was surprised that FDA would take such a reckless action as removing Tirzepatide from the shortage list knowing that a strike might impact supply without waiting first to see how long the strike would last and whether supply would in fact be impacted.

FDA's Delisting Action Causes Severe Harm to OFA and Its Members

37. Because FDA removed Tirzepatide from the shortage list, and because Tirzepatide is not on the clinical need list, bulk compounding of Tirzepatide is now categorically unavailable under Section 503B and thus is prohibited to all OFA's members and all FDA-registered 503B outsourcing facilities.

38. As noted above, all OFA's members are outsourcing facilities or are affiliated with outsourcing facilities that operate under Section 503B. Because a shortage listing is a necessary prerequisite to compounding under Section 503B if a bulk drug substance is not listed on the 503B Bulks List, Tirzepatide is not listed on the 503B Bulks List, FDA's action categorically bars every OFA member from compounding Tirzepatide.

39. FDA's delisting decision closes off an important source of market supply that met a sweeping scope of demand up until the decision. OFA members have produced hundreds of thousands of doses of compounded Tirzepatide in September 2024 alone, which moved promptly from their storage to pharmacies and other lawful purchasers, reflecting continued high demand and short supply.

40. OFA members are aware of thousands of unique customers in recent weeks unable to access branded forms of Tirzepatide. There is every reason to believe that cutting off supply through compounding will leave patient needs unfilled on a large scale, which will in turn exacerbate the public-health crises of obesity and diabetes. OFA is continuing to receive information of shortages, including from patients and consumers unable to obtain Tirzepatide products.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on the 8th day of October, 2024.

DocuSigned by:

A370BF7EF0BF479...

Lee Rosebush

Exhibit 1

[Skip to main content](#)

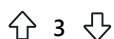
r/Zepbound

[Search in r/Zepbound](#)[Log In](#) **r/Zepbound** • 4 mo. ago
Love2Garden59

Compounded to brand name better/worse?

Experience

Hi all: I started with compounded tirzepatide on 4/28. I am paying OOP so cost is a big factor. I am a slow loser. I was able to locate a box of 7.5 ZB and bought it with Lilly's coupon for \$550 and will start it next Wed. Has anyone had better or worse results with this switch? My scientific brain says there's no difference between the two drugs but wondering what other people's experience is?



31



Share

Add a Comment

Sort by: Best ▾

Search Comments

**PD77a6** • 4mo ago •

I have been on both -I noticed more suppression and weight loss on zep vs compound-but that was just my experience



Reply



1 more reply

**Dr_Scorpion_** • 4mo ago • Edited 4mo ago •

I haven't tried compounding, but a pharmacist at my PCP's office explained it to me like this and I loved the analogy: "Compounders follow a recipe. Just like with a dish from your favorite restaurant, you can try to make it at home, but it probably won't be the same. A better chef can make a very close approximation. You just have to find that better chef." At the time, she was recommending that I stick with Zep, because she reached out to her trusted compounders for me and none of them were making Terzepatide. Note: she didn't have a problem with compounding, she just wanted to personally know who was making it to give her recommendation.

Edit: typo and note



Reply



2 more replies

**overit901** • 4mo ago •

I take both, and for me Zepbound is notably stronger. Compound still works, but I have to take more of it to get similar effects.



Reply



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Pharm grade is always going to be better, it has to contain exactly what it says on the packaging otherwise Lilly is getting serious fines

The compounding pharmacy isn't testing every batch of tirzepatide powder that they buy from Chinese factories (and the FDA doesn't require them to do so) so you may get denatured raw materials or lower purity than expected

Pharm grade from Lilly has to pass extensive testing and is manufactured in a billion dollar FDA approved facility, not a Chinese chemical factory that also makes weedkiller and fertilizer.

↑ 13 ↓ [Reply](#) ...



suefallsalot • 4mo ago •

No difference for me

↑ 6 ↓ [Reply](#) ...



Miserable_Debate_985 • 4mo ago •

People who took both told me they felt some difference mostly in a positive way towards the Lily products, I can afford Lilly but I choose to stay with Compounding for several reasons , I just don't trust the coupon will stay the same and the availability is not guaranteed as well. And I like the flexibility of the dosing with the compounding and I like to support local businesses.

↑ 5 ↓ [Reply](#) ...



AmuzeYou • 4mo ago •

I didn't notice a difference

↑ 7 ↓ [Reply](#) ...



Love2Garden59 [OP](#) • 4mo ago •

I guess like everything else it is different for each person :)

↑ 3 ↓ [Reply](#) ...



rreehling • 4mo ago •

No differences for me. Love compounding flexibility and price.

↑ 3 ↓ [Reply](#) ...



Madrugada_Quente • 4mo ago •

[Skip to main content](#)[Log In](#)

shot day, but not too much. I'm not sure if this is the doses between compound and zep or just between the dosage levels of 5 to 7.5. What do like is that after not having any side effects on any dose until starting 7.5, I have more control on the dosage with a vial and syringe. I lessened my dose to 6.5 and all of the horrible side effects went away. I know I'm losing a lot of weight based on my clothes since moving up, but I don't weigh myself for another 2 weeks. For now, because I'm OOP, I'm staying on compound as long as I can. I even told my pharmacy to keep the 7.5 and give it to someone else when they finally called and said they had it back in stock (5.5 weeks later). Compound ships directly to my door and is almost \$200 cheaper, and works great, if not better.

↑ 3 ↓ Reply ...

⊕ 1 more reply



kevink4 • 4mo ago •

Some reported Compound better. Some Brand name better. Others see no difference.

↑ 5 ↓ Reply ...



Ok-Yam-3358 • 4mo ago •

If the compound is real/done correctly, you shouldn't notice a meaningful difference.

↑ 3 ↓ Reply ...



[deleted] • 4mo ago •

There should be no difference. Raw materials are at a risk of being not as high grade but a good compounding pharmacist does their due diligence and tries to use trusted sources.

↑ 2 ↓ Reply ...



[deleted] • 4mo ago •



TileMaven • 4mo ago •

i take both. no difference for me.

↑ 2 ↓ Reply ...



BlondEpidemiologist • 4mo ago •

No difference for me

↑ 2 ↓ Reply ...



midnitekitten • 4mo ago •

Skip to main content

Log In

losing weight at a good/safe rate (about 2lbs per week).

2 Reply ...



Pretend-Kitchen-6631 • 4mo ago •

I did my first compound on Thursday and so far I don't feel and difference other than super mild nausea.

2 Reply ...



BustedCanofBiscuits • 4mo ago •

No difference for me.

2 Reply ...



IrishGinger001 • 4mo ago •

I haven't noticed a difference, really. Except for saving money on compound.

2 Reply ...

[View more comments](#)

[r/Zepbound](#)

A 4. Finally!!

2.5K upvotes · 182 comments



[r/Zepbound](#)

357-120

1.7K upvotes · 204 comments



[r/Zepbound](#)

Finally hit 100 lbs!!!

1.2K upvotes · 53 comments



[r/Zepbound](#)

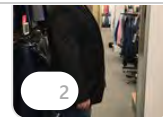
September Check in



Skip to main content

Log In

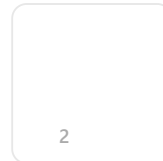
Down 100lbs thanks to Zepbound



1.1K upvotes · 59 comments

r/Zepbound

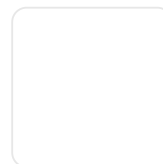
80 pounds down 🙏



1K upvotes · 72 comments

r/Zepbound

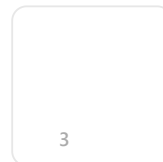
Goal... finally!!



1K upvotes · 76 comments

r/Zepbound

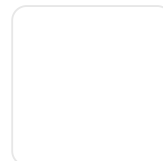
I never imagined I'd see this day



1K upvotes · 60 comments

r/Zepbound

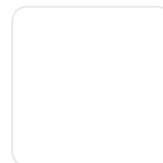
95lbs gone



987 upvotes · 41 comments

r/Zepbound

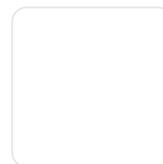
Welcoming me back



901 upvotes · 62 comments

r/Zepbound

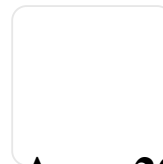
The end of last November I started Zepbound. I (37f - 5'6") was 236.4 and had been diagnosed with a non-alcoholic fatty liver. Last week I weighed in at 187.4, I no longer have issues with my liver, and I...



862 upvotes · 49 comments

r/Zepbound

Hit my target!



[Skip to main content](#) [Log In](#)

117 days in

700 upvotes · 43 comments

r/Zepbound

5 months, 44 pounds down!

688 upvotes · 70 comments

r/Zepbound

Someone finally noticed!

681 upvotes · 44 comments

r/Zepbound

80lbs Down w/Zep

584 upvotes · 57 comments

r/Zepbound

finally lost 50!

570 upvotes · 36 comments

r/Zepbound

I'm so upset right now

556 upvotes · 154 comments

r/Zepbound

Officially 30 lbs down!

554 upvotes · 18 comments

r/Zepbound

I can actually see it 🥹

553 upvotes · 30 comments



Log In

523 upvotes · 24 comments

r/Zepbound

30lbs lost vs 80lbs lost

496 upvotes · 14 comments

r/Zepbound

8 Months 75 pounds down 🙏

492 upvotes · 25 comments

r/Zepbound

Face shot progress

491 upvotes · 64 comments

r/Zepbound

Got my script today, 100% covered!

464 upvotes · 94 comments

Exhibit 2

HEALTH NEWS

Some doctors are embracing compounded versions of popular weight loss drugs

During shortages, the FDA allows compounding pharmacies to make versions of drugs that are "essentially a copy" of brand-name medicines.



— Compounding pharmacists buy their ingredients from FDA-registered facilities that synthesize the active ingredients in demand. Jaap Arriens / NurPhoto via Getty Images file

Aug. 16, 2024, 5:00 AM EDT

By Berkeley Lovelace Jr., Jason Kane and Stephanie Gosk

Some health care providers say they're starting to feel more comfortable prescribing compounded versions of the blockbuster weight loss drugs Wegovy and Zepbound, even as others have lingering concerns about the ingredients used in them.

It has been no secret that, even with a prescription in hand, the weight loss drugs can be hard to get hold of. They're pricey – a month's supply can cost more than \$1,000 – and are often in shortage.

ADVERTISING



THE OFF-ROAD READY
2025 MAZDA CX-50

Compounded versions of [semaglutide](#) (the drug found in Wegovy) and tirzepatide (the drug in Zepbound), on the other hand, often come at lower prices and are much easier to get.

“Not only are physicians more OK with prescribing compounded GLP-1 medications, but they are also advocating for them,” said Dr. Shauna Levy, a specialist in obesity medicine and the medical director of the Tulane Bariatric Center in New Orleans, referring to the class of drugs that include Wegovy and Zepbound.

At Duke Health's Hillsborough Primary Care Center in North Carolina, providers have been prescribing [compounded versions of the drugs](#) while the brand-name versions are in shortage.

Leanne Owens, a physician assistant at the practice, said she prescribed 10 of her patients [compounded versions](#) of the weight loss drugs after the state stopped covering the brand-name versions for state employees in April.

Initially, she said, she was nervous about prescribing compounded weight loss medications because she had never done it before. However, after she spoke with a compounding pharmacist at Duke, she felt reassured.

“Is this truly the medication? And is the recipe the same recipe that's being used by the commercial drug manufacturers?” Owens recalled thinking. “Anything that is new that we are considering offering to a patient, we want to make sure that we have done our research.”

Owens isn't alone – other members of the medical practice have also turned to compounded versions of weight loss drugs.

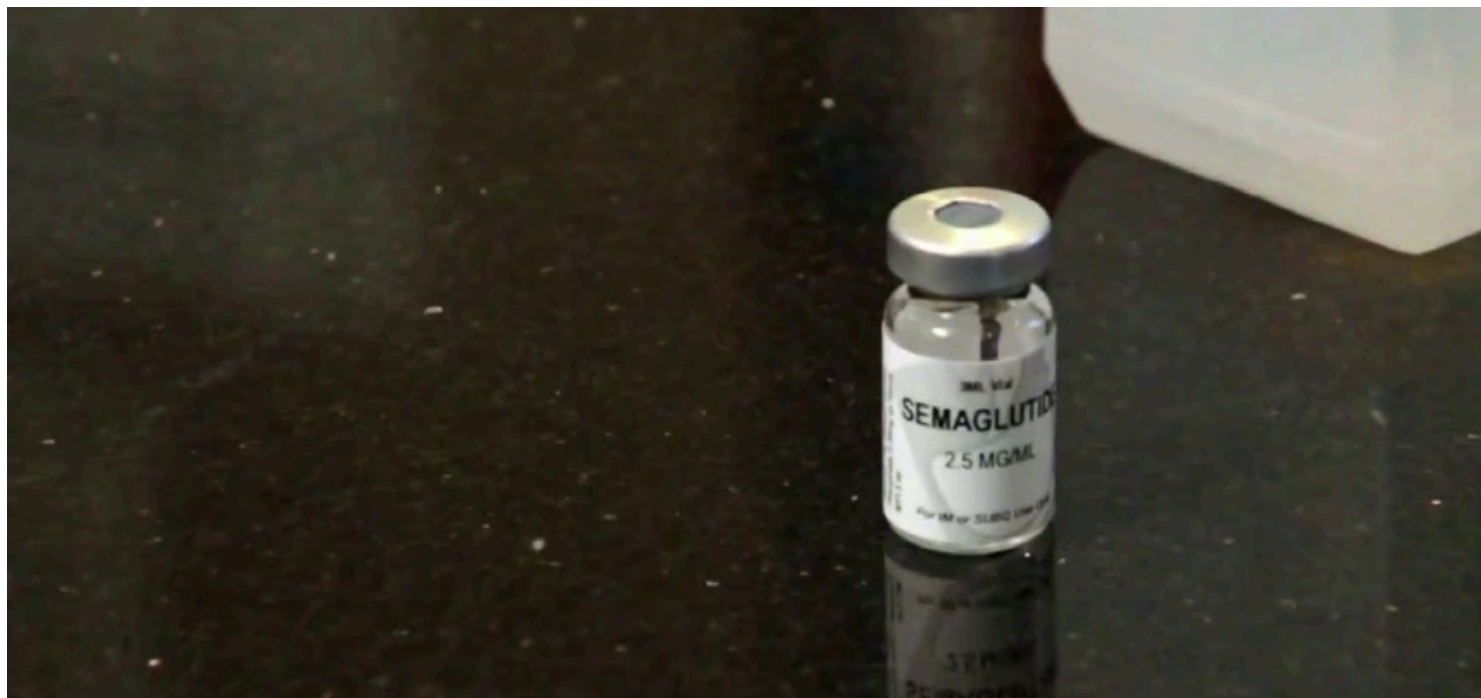
What is compounding?

People use compounded versions of drugs for a number of reasons. A compounding pharmacy can take a drug that comes only in tablets and reformulate it into a liquid for a patient who can't swallow a pill, or it can make a version of a drug without a certain dye, for example, if a patient is allergic to it.

Compounding also comes into play during [drug shortages](#): The Food and Drug Administration allows compounded versions that are “essentially a copy” of commercially available drugs under special circumstances such as those.

Weight loss drug shortages prompt pharmacies to make similar medications

02:45



Semaglutide for weight loss has been in shortage since 2022, according to the [FDA's drug shortage database](#). Tirzepatide, which was approved for weight loss in the U.S. only in November, went into shortage in April and [is currently in shortage, the agency says](#).

Both drugs are under patent, and Novo Nordisk and Lilly don't supply the ingredients to outside groups, raising questions about what's being sold to consumers.

Compounding pharmacists, however, typically purchase their ingredients from FDA-registered facilities that themselves can't buy the active ingredients from the drugmakers.

The facilities can essentially replicate or produce copies of the active ingredients in demand, according to the FDA. Unlike for generic drugs, the agency [doesn't test or verify the ingredients](#), however; that's up to the pharmacists. Experts say it's important that doctors prescribe the drugs from compounding pharmacists they can trust. Patients should get prescriptions from their doctors and fill them at state-licensed pharmacies. Patients should also avoid ordering drugs online or buying them from med spas.

It's also important for providers to advise patients about on how to measure doses accurately. Last month, the [FDA reported](#) that it had received reports of patients' overdosing on compounded semaglutide, which caused some to be hospitalized. The dosing errors, the agency said, were due to patients' measuring and giving themselves incorrect doses, as well as providers' miscalculating the drugs' dosage.

Matthew Brown, the pharmacy manager at the Duke Compounding Facility, said the center uses only state-licensed pharmacies that Duke has vetted to compound medications that it doesn't make itself, including semaglutide. It provides other compounding pharmacy services for the university's entire health system, including the Hillsborough Primary Care Center.

Brown said Duke prescribes compounded versions of the weight loss medications only when there are shortages. Once the shortages have ended, it will switch back to prescribing the brand-name drugs, he said.

Owens, the physician assistant, said she trusts that the compounded versions are the same medications, noting that patients are losing weight. She said she hasn't seen an increase in side effects.

Elizabeth Kenly, 58, of Graham, North Carolina, was prescribed a compounded version of tirzepatide by a doctor at the Hillsborough practice in March after she had trouble finding Wegovy because it was in shortage. Since she started the compounded drug, she has lost 25 pounds and wants to lose another 25.

"I was a little nervous. I was like, 'What is a compounded medication?'" Kenly said. "I felt really comfortable after talking to my doctor."

For some, too many unknowns

Even though more doctors are open to prescribing the compounded weight loss drugs, Novo Nordisk and Eli Lilly staunchly oppose the practice.

Both have filed multiple lawsuits against compounding pharmacies, weight loss clinics and medical spas. In statements to NBC News, the drugmakers said the drugs lack the same oversight as FDA-approved medicines and pose risks to patients.

A spokesperson for Novo Nordisk described the compounding system as “not working as intended.”

“Novo Nordisk will continue to take legal action against compounding pharmacies and other entities engaged in unlawful marketing and sales of unapproved compounded ‘semaglutide’ drugs,” the spokesperson said.

Lilly spokesperson Antoinette Forbes said in a statement, “Poison control centers, regulators, and patient advocacy groups around the country are issuing warnings about the use of compounded anti-obesity products.”

Many doctors are still uncertain, as well.

“In theory, if you can get everything right, it can be a reasonable product. But the problem is that there are so many things that could go wrong,” said Dr. Scott Isaacs, president-elect of the American Association of Clinical Endocrinology. “Definitely there may be more doctors prescribing it, but from an organizational and professional perspective, there’s more and more warnings.”

“Not everybody is probably doing it like Duke,” Isaacs said.

Dr. Christopher McGowan, a gastroenterologist who runs a weight loss clinic in Cary, North Carolina, said he frequently hears about patients who have tried compounded weight loss drugs. However, he said, he would be “very hesitant” to prescribe them himself.

“In my opinion, there are still too many unknowns about compounded versions of semaglutide and tirzepatide,” McGowan said. “Regardless of whether a pharmacy is accredited or not, the actual compound is not monitored, regulated or tested by the FDA. For patients, there is no guarantee of what they are receiving and whether it is equivalent to a brand-name drug.”

Dr. Daniela Hurtado Andrade, an endocrinologist at the Mayo Clinic in Jacksonville, Florida, said she has begun to see more patients in her clinic who have already started on compounded versions of the drugs. However, when she sees them, she often suggests alternative weight loss drug options – such as combination treatments of phentermine and topiramate (sold together as the drug Qsymia) or naltrexone and bupropion (the drug Contrave) – if the brand-name drugs aren’t available.

“People are focused on the fact that the only options available for the treatment of overweight and obesity are the new injectable medications. This is absolutely not true,” Andrade said. “There are other anti-obesity medications that are also effective and are not as expensive.”



Berkeley Lovelace Jr.

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Jason Kane

Jason Kane is a producer in the NBC News Health & Medical Unit.



Stephanie Gosk

Stephanie Gosk is an NBC News correspondent based in New York City. She contributes to "Nightly News with Lester Holt," "TODAY" and MSNBC.

Exhibit 3



r/compoundedtirzepatide • 7 days ago

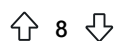
kiiizuato

...

Zep to compound?

Discussion

I have an appointment with my endocrinologist next week and I want to discuss more in depth with him about switching to compound tirzepatide. I feel like I'm not educated enough to do the switch (also scared) because I've been on zepbound since June. And honestly, spending \$800 every month on Zep is just getting really expensive. He's very open to me switching, we talked about it briefly last month and I know a pharmacy that does compound. I guess, I just need help and more knowledge? If anyone could explain their experiences and how they like the compound vs. the brand, I'd appreciate it! I'm on 10mg.



8



23



Share

[Single comment thread](#)[See full discussion](#)

Madrugada_Quente • 7d ago •

Started in March on Mounjaro, moved to Zep the next month...then couldn't find either and started month 3 on compound. I have lost over 50lbs and gone down 10 sizes (18 to 8). Compound is delivered directly to my door, currently paying \$375 per month (my insurance doesn't cover it)...and what I like is that when titrating up, I do it by .5mg-1, not 2.5 - which is what you have to do with pens. Zero side effects doing it this way for me and I can stay on a lower dose longer. I will use compound until they no longer allow it to be sold. I absolutely love it!! Best of luck to you - you'll do great!!



11



Reply

...



CuppyCupperton • 7d ago •

Would you mind sharing who you use for your compound?



3



Reply

...



Madrugada_Quente • 6d ago •

Emerge, fulfilled through Hallandale.



2



Reply

...



Cmar9399 • 7d ago •

Hello, can you explain what you mean by ".5mg-1? Do you mean that if you started at 2.5mg you would titrate .5mg up to 3?



2



Reply

...



Madrugada_Quente • 6d ago •

[Skip to main content](#)[Log In](#)

jumping up 2.5mg at a time. When I went from 2.5 to 5, I didn't have any problems. It started with the higher doses.

↑ 2 ↓ [Reply](#) ...



TurnerRadish • 4d ago •

It's truly one of the great advantages of compound. You aren't locked into titrating up by 2.5mg each time you increase your dosage. I move up exactly like the other commenter does—.5mg or 1mg at a time. It makes the transition so smooth.

↑ 2 ↓ [Reply](#) ...

r/compoundedtirzepatide

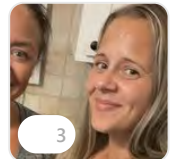
officially overweight!! 🤔🤔🤔

116 upvotes · 20 comments

r/compoundedtirzepatide

Weight Loss So Far

115 upvotes · 14 comments



r/compoundedtirzepatide

Let's hear it for the girls!

115 upvotes · 34 comments

r/compoundedtirzepatide

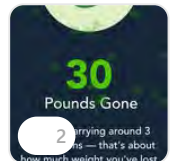
Lessons from a "slow loser"

99 upvotes · 28 comments

r/compoundedtirzepatide

Almost to the halfway point!

56 upvotes · 7 comments



r/compoundedtirzepatide

The results are in and they are amazing!!

53 upvotes · 6 comments

r/compoundedtirzepatide

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[Log In](#)

r/compoundedtirzepatide

So far I've lost 60lbs with Zep and compound.

45 upvotes · 19 comments

r/compoundedtirzepatide

EMERGE experience

42 upvotes · 24 comments



r/compoundedtirzepatide

Dr sent the Rx to the compounding pharmacy!!

38 upvotes · 13 comments

r/compoundedtirzepatide

Amble vs Lavender Sky Health vs Mochi

33 upvotes · 40 comments

r/compoundedtirzepatide

60 lbs down!

28 upvotes · 6 comments

r/compoundedtirzepatide

Thank you

28 upvotes · 8 comments

r/compoundedtirzepatide

My transition from Zep to Compound

26 upvotes · 13 comments

r/compoundedtirzepatide

Moving from Emerge to Lavender Sky - experiences?

17 upvotes · 60 comments

r/compoundedtirzepatide

first dose

17 upvotes · 6 comments

r/compoundedtirzepatide

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r/compoundedtirzepatide

Buying in bulk

16 upvotes · 34 comments

r/compoundedtirzepatide

Week 3 Down

14 upvotes · 6 comments

r/compoundedtirzepatide

Best Way to get Electrolytes? (Headaches)

14 upvotes · 37 comments

r/compoundedtirzepatide

Just 2 drinks

13 upvotes · 5 comments

r/compoundedtirzepatide

[California] Orderly Meds: If you ever thought about titrating up one last time before maintenance, to make the vial last longer... Don't! They don't play that.

13 upvotes · 37 comments



r/compoundedtirzepatide

Refrigeration

13 upvotes · 37 comments

r/compoundedtirzepatide

For those of you who have tried a few, what's your favorite provider/pharmacy combo?

11 upvotes · 80 comments

r/compoundedtirzepatide

Same weight I was years ago but still have a belly

11 upvotes · 24 comments

Exhibit 4



Ro > Weight loss > GLP-1 >

How much does tirzepatide cost with and without insurance?



Reviewed by Patricia Weiser, PharmD,

Written by Angela Myers

LAST UPDATED: SEP 29, 2024 5 MIN READ

Key takeaways

- The list price for a month supply of tirzepatide is \$1,069.08 for Mounjaro and \$1,059.87 for Zepbound. The drugs' manufacturer and pharmacies offer additional savings programs and discounts.
- With insurance, both Zepbound and Mounjaro can cost as little as \$25 per month. The exact price will depend on your specific policy, if you've met your deductible, and the prescribed brand-name drug.

HERE'S WHAT WE'LL COVER

01 How much does tirzepatide cost without insurance?

02 Does insurance cover tirzepatide?

03 How to get tirzepatide

04 Frequently asked questions: tirzepatide cost

Ever since weight loss injections were released, they've gotten a lot of attention. And while the FDA approved tirzepatide to help manage weight and to treat type 2 diabetes, sometimes the cost can be prohibitive for many people.

The list price without insurance or discounts ranges from \$1,059.87 to \$1,069.02 per month. The price you'll pay depends on the drug prescribed (e.g. Mounjaro or Zepbound), your health insurance (if any), and other factors. While compounded tirzepatide can be more affordable, the price still starts at \$299 or more per month.

Fortunately, there are ways to save on tirzepatide. Ahead, we discuss the costs for different tirzepatide prescriptions on the market, the best ways to save money, and when insurance does (and doesn't) cover the drug.

Mounjaro Important Safety Information: [Read more about serious warnings and safety info.](#)

Zepbound Important Safety Information: [Read more about serious warnings and safety info.](#)

Weight loss

Get Zepbound

Lose up to 20% body weight in a year, if prescribed.

Get started

Weight loss claims apply to branded medications. Limited availability of some doses of Zepbound. See [Important Safety Information](#)



How much does tirzepatide cost without insurance?

The price for tirzepatide without insurance is typically under \$1,200, but may be less depending on discounts and coupons.

Before we dig deeper into the financials, a quick refresher: tirzepatide is a dual glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP) receptor agonist. That's a long winded way to say tirzepatide mimics two gut hormones, resulting in improved glycemic control and managing body weight.

If this sounds similar to semaglutide (i.e. Ozempic, Wegovy, and Rybelsus), that's because the two are alike, though research suggests tirzepatide may be more effective for weight loss.

Currently, tirzepatide is available in two FDA approved brand-name prescription drugs: Zepbound and Mounjaro. It's important to note that both work better alongside diet and exercise, and they are approved for different purposes. But more on that later. For now, let's dive into how much they cost.

Ozempic Important Safety Information: [Read more about serious warnings and safety info.](#)

Wegovy Important Safety Information: [Read more about serious warnings and safety info.](#)

Mounjaro

With a list price of \$1,069.08 for four pre-filled pens, Mounjaro can be expensive.

The good news? Most individuals with a prescription for Mounjaro will pay less. Even if you don't have access to health insurance or assistance programs, most pharmacies charge less than the list price.

Eli Lilly also offers a Mounjaro savings card where commercially insured patients (aka those not insured through Medicare, Medicaid, or another government-funded insurance program) can get Mounjaro for as little as \$25 a month. If you have commercial insurance coverage that doesn't include Mounjaro, the savings card provides up to \$473 off the monthly prescription. Sadly, the savings program doesn't extend to those who are uninsured or insured by a noncommercial payer.

With that in mind, here's how much Mounjaro (four 5 mg/0.5ml pens) costs at different pharmacies, according to SingleCare.

Walgreens	\$934.98
CVS	\$991.47
Walmart	\$1,013
RiteAid	\$995.46

**While prices were valid at the time of publication, they may vary based on date and location.*

Zepbound

The list price for a one-month supply of Zepbound is \$1,059.87 for four pens (a monthly supply).

Eli Lilly is also the manufacturer of Zepbound, and their savings card offers the same discount for Zepbound: a price as low as \$25 monthly, if commercially insured. For those without insurance, the LillyDirect service does offer a “cash price” of \$399 for a monthly Zepbound prescription of a 2.5 mg vial or \$549 monthly for a 5mg vial.

Along with discounts and insurance coverage, factors like your pharmacy and zip code can impact the final price. Here’s an idea of how much four 2.5 mg/0.5ml pens of Zepbound cost at four pharmacies, according to SingleCare:

Walgreens	\$936.56
CVS	\$993.81
Walmart	\$1,015
RiteAid	\$997.62

**While prices were valid at the time of publication, they may vary based on date and location. For the most accurate estimates, refresh the SingleCare searches and enter your zip code.*

Compounded tirzepatide

Compounded drugs are custom-made based on a patient’s prescription. While these drugs are allowed under federal law, they don’t have FDA approval and may not have undergone a robust safety and manufacturing review.

Compounded tirzepatide features the same active ingredients as Mounjaro and/or Zepbound, with a few financial caveats. First, it is usually not covered by insurance. However, the list price can be more affordable than Zepbound or Mounjaro. For example, Ro offers a compounded tirzepatide starting at \$299 per month for those who qualify.

How to save on the cost of tirzepatide without insurance

Let’s face it: paying upwards of \$1,000 a month for tirzepatide may be out of budget. Luckily, there are ways to save.

The first is through the manufacturer's discount programs:

- **If uninsured or insurance doesn’t cover Zepbound:** Eli Lilly offers capped cash price of \$399-\$549 for Zepbound vial, depending on dosage, through LillyDirect.

- **If insurance doesn't cover Mounjaro:** you may enjoy up to \$473 off. This discount, however, is reserved for those who are commercially insured, but Mounjaro isn't covered by that commercial insurance plan.
- **If commercial insured:** you may be able to get both Zepbound or Mounjaro for as little as \$25 a month, so long as your commercial insurance plan covers the prescription.

Does insurance cover tirzepatide?

Insurance coverage for tirzepatide is a bit of a gray area. Some commercial health insurance plans cover Mounjaro, Zepbound, or both. When they do, the savings can be huge (for example, some insured individuals pay \$25 for their monthly prescription of Mounjaro or Zepbound). It's unlikely, however, that your insurance will cover compounded tirzepatide.

If neither is covered but you are commercially insured, Eli Lilly offers up to \$473 off a monthly prescription of *Mounjaro only*. There are more affordable cash prices for Zepbound, no matter your health insurance status (to recap: the cash prices range between \$399-\$499, depending on dosage).

When Zepbound, Mounjaro, or both are covered by your plan, they will be listed in your insurance plan's drug formulary. If not listed, you and your doctor can request prior-authorization when the prescription is a medical necessity. The Obesity Action Coalition offers a templated prior-authorization request and other resources to help you navigate insurance coverage.

Does Medicare cover tirzepatide?

Most Medicare Advantage and Part D prescription drug plans don't cover tirzepatide. However, they are not prohibited from covering these (when prescribed for Type 2 diabetes), meaning your plan *may* cover Zepbound, Mounjaro, or both. If covered, you may still be responsible for part of the cost, depending on your plan's deductible and copays.

If tirzepatide is prescribed for weight loss specifically, Medicare cannot cover the cost—even if your plan is through a Medicare Advantage provider. Organizations are advocating for this law to be changed, and a bill in congress may change this in the near future.

Does Medicaid cover tirzepatide?

Unlike Medicare, which has national standards for what is and isn't covered, Medicaid coverage varies by state. Contact your state Medicaid agency or review your plan's drug formulary to determine if tirzepatide is covered. Medicaid eligibility is contingent upon income requirements set by individual states.

How to get tirzepatide

Since tirzepatide is a prescription drug, they require a Rx from a healthcare provider. If you believe tirzepatide may be a good fit, schedule an appointment with a healthcare provider who can assess your symptoms and determine the best treatment plan.

Alternatively, you can get a tirzepatide prescription through Ro's program that offers:

- A personalized treatment plan
- 1:1 health coaching
- Ongoing support from healthcare providers
- Insurance concierge services to help navigate tirzepatide coverage

No matter which option you choose, it's important to remember that Zepbound, Mounjaro, and compounded tirzepatide work best in tandem with diet and exercise. Plus, the two brand-name prescriptions are FDA-approved for different medical needs.

Zepbound is FDA-approved for chronic weight management in adults:

- with a BMI of 30 kg/m² or greater
- with a BMI between 25 kg/m² and 30 kg/m² and one or more weight-related conditions (i.e. high cholesterol, high blood sugar levels, high blood pressure, or type 2 diabetes)

Mounjaro is FDA-approved for type 2 diabetes, but not weight loss. Sometimes, physicians prescribe Mounjaro off-label for weight loss to patients who have overweight or obesity but don't have type 2 diabetes. This was more common before Zepbound was FDA-approved for weight loss, though it still occurs.

Compounded tirzepatide is not FDA-approved, but is legally available. Zepbound, Mounjaro, and compounded tirzepatide may cause side effects, including nausea, headaches, and stomach pain, which is another reason why it is important to follow the advice of your doctor when deciding between medications.

Frequently asked questions: tirzepatide cost

How much does tirzepatide cost per month?



What is the cheapest way to get tirzepatide?



The cheapest way to get tirzepatide depends on your insurance coverage, location, and other factors. For those who are commercially insured (and Zepbound or Mounjaro are covered by their plan), Eli Lilly offers a discount card for either medication for as little as \$25 a month. Those with commercial insurance that doesn't cover Mounjaro can also enjoy up to \$473 off that prescription only.

For those who are uninsured or insured by Medicare or Medicaid, LillyDirect offers a cash price of \$399-\$549 for Zepbound, with the exact price determined by dosage. Specific pharmacies (like Costco) and organizations like Optum Perks and WellRX offer additional savings. Compounded tirzepatide, which can cost as little as \$299 per month, may also be an affordable alternative if uninsured or underinsured.

Will insurance cover tirzepatide?



DISCLAIMER

If you have any medical questions or concerns, please talk to your healthcare provider. The articles on Health Guide are underpinned by peer-reviewed research and information drawn from medical societies and governmental agencies. However, they are not a substitute for professional medical advice, diagnosis, or treatment.

References

Weight Loss

How we reviewed this article

Every article on Health Guide goes through rigorous fact-checking by our team of medical reviewers. Our reviewers are trained medical professionals who ensure each article contains the most up-to-date information, and that medical details have been correctly interpreted by the writer.

Current version

September 29, 2024

Written by

Angela Myers

Fact checked by**Patricia Weiser, PharmD**

About the medical reviewer



Patricia Weiser, PharmD

Patricia Weiser, PharmD, is a licensed pharmacist, health content writer, and medical reviewer with more than a decade of clinical experience in community and hospital pharmacy.

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How to switch from
semaglutide to tirzepatide



**Get
started
with a
special
intro
offer**

Exhibit 5

CBS SATURDAY MORNING

While brand-name weight loss drugs are in short supply, a market for alternatives thrives



By Julia Ingram, Alex Clark

Updated on: September 21, 2024 / 9:00 AM EDT / CBS News

Prescription weight loss drugs have become so popular in the United States that suppliers have struggled to keep up. Jean Readdy, a retired teacher living in Sinking Spring, Pennsylvania, is among the one in eight Americans who

have tried a GLP-1 drug for weight loss or diabetes, more commonly known by brand names like Ozempic and Wegovy.

Readdy, who has struggled with her weight for most of her life, told CBS News her weight affected her self-esteem and how she moved through the world.

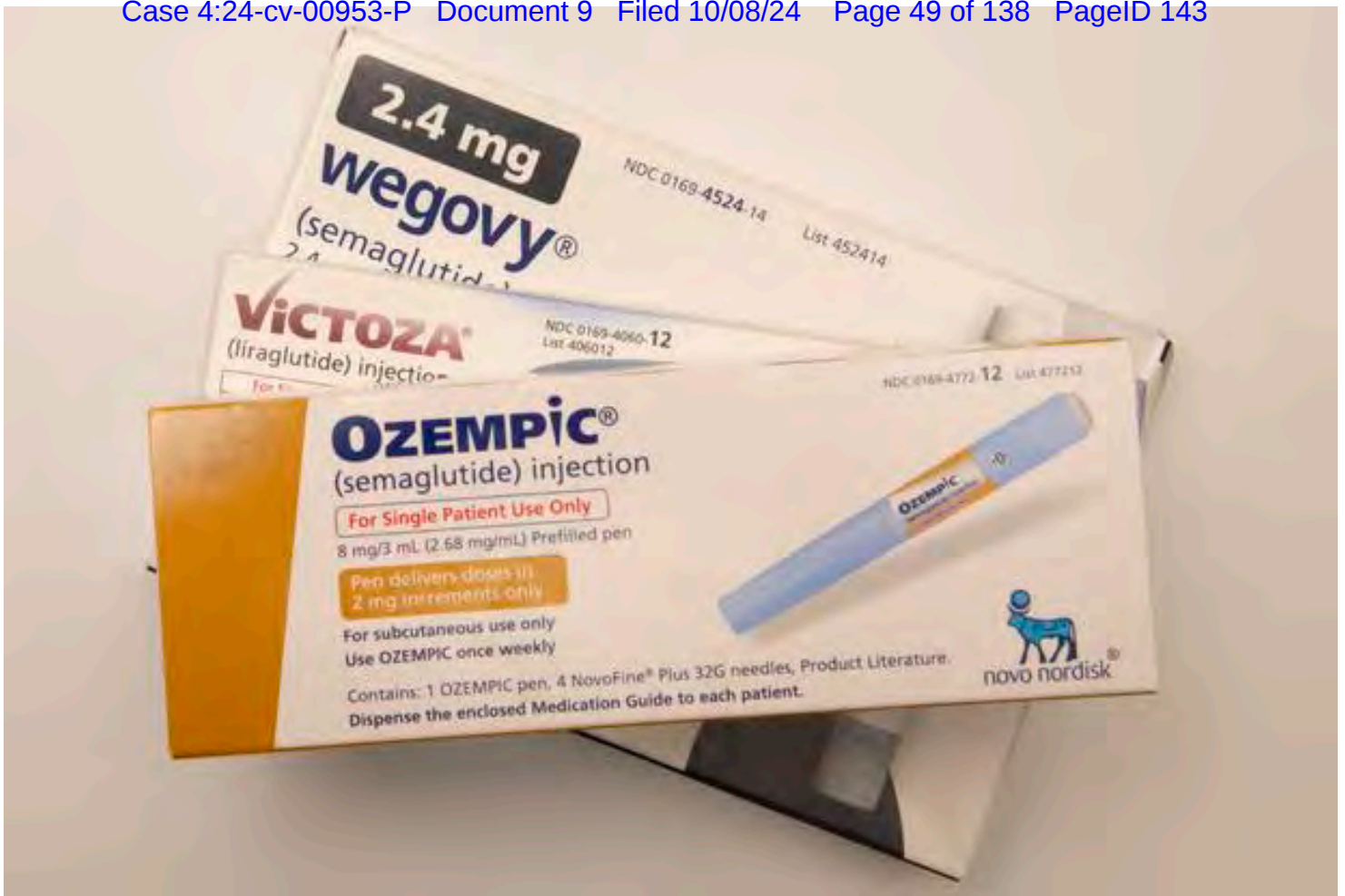
"I didn't like going out places," Readdy admitted.

She reached her highest weight last October, right as her son was about to be married.

"I was embarrassed for him and I was embarrassed for myself," said Readdy.



Now, she's one of a growing number of people turning to compounded drugs: reformulated versions the FDA has permitted pharmacies to distribute during an ongoing shortage of brand-name drugs.



The big three injectable prescription weight loss medicines are Ozempic, Victoza and Wegovy.

MICHAEL SILUK/UCG/UNIVERSAL IMAGES GROUP VIA GETTY IMAGES

Readdy's decision to switch from a name brand to a compounded drug came down to price and availability. Paying \$1,200 a month for the name-brand drug Zepbound wasn't sustainable, and it was becoming impossible to find, she said.

And she's not alone.

Readdy turned to online communities where thousands of people shared resources and where to find the drugs in short supply. On a Reddit forum, she read about the side effects, learned about alternatives, and eventually came across a spreadsheet with dozens of telehealth providers for prescription drugs used for weight loss. After weighing the risks and calling dozens of pharmacies, she eventually found one that provided her with injectable tirzepatide, the same active ingredient found in Zepbound. Readdy now pays \$399 a month for her compounded medication.

①

CBS News identified more than 100 companies advertising access to tirzepatide or semaglutide, both active ingredients in name-brand GLP-1 drugs that regulate insulin and suppress appetite.

LegitScript, an organization that monitors and certifies online businesses, said it saw a 94% increase in companies applying for its healthcare certification since 2023. More than half of its recent applicants had a weight-loss focus

However, compounded drugs aren't reviewed for efficacy and safety by the FDA.

"There is not a tremendous amount of oversight," said CBS News medical contributor Dr. Celine Gounder. "There is a wide range in terms of the quality and the risks."

Researchers who ordered and tested compounded semaglutide found some were contaminated and others contained more of the active ingredient than advertised.

Compounded drugs typically come with a needle and a vial, rather than a pre-filled pen, as the brand-name medications do. This can make them harder to administer and lead to potential dosing errors. The FDA issued warnings about administering the proper dosage of the drugs and the risks of using compounded semaglutide.

Still, many of the telehealth companies advertising compounded weight-loss drugs present them as the same as or "generic" versions of the brand-name medications. Nearly a quarter of the websites that CBS News identified did not disclose the drugs they were advertising were compounded.

There is no FDA-approved generic version of brand-name weight loss drugs since pharmaceutical companies still hold patents on the medications. Some of the companies falsely claimed the drugs were FDA-approved. A few even allowed direct purchases without the required prescription.

The FDA is working closely with drugmakers and may restrict the manufacturing of compounded drugs as more versions of approved drugs come off the shortage list.

Last month, Eli Lilly announced it would reduce the cost of the lowest dose of its drug Zepbound to around \$400 a month. It also launched its own telehealth company, LillyDirect.

Readdy, who has lost more than 50 pounds, said she intends to continue using her compounded medication.

"We're very afraid actually that the drug is gonna be taken away," she said. "I think it's a miracle drug."

Exhibit 6

Why millions are trying alternatives to Big Pharma's weight loss drugs



By Arthur Allen
July 20, 2024 / 7:00 AM EDT / KFF Health News



Pharmacist Mark Mikhael has lost 50 pounds over the past 12 months. He no longer has diabetes and finds himself "at my ideal body weight," with his cholesterol below 200 for the first time in 20 years. "I feel fantastic," he said.

Like millions of others, Mikhael credits the new class of weight loss drugs. But he isn't using brand-name Wegovy or Zepbound. Mikhael, CEO of Orlando, Florida-based Olympia Pharmaceuticals, has been getting by with his own supply: injecting himself with copies of the drugs formulated by his company.

He's far from alone. Mikhael and other industry officials estimate that several large compounding pharmacies like his are provisioning up to 2 million American patients with regular doses of semaglutide, the scientific name for Novo Nordisk's Wegovy, Ozempic and Rybelsus formulations, or tirzepatide, the active ingredient in Eli Lilly's Zepbound and Mounjaro.

The drug-making behemoths fiercely oppose that compounding business. Novo Nordisk and Lilly lump the compounders together with internet cowboys and unregulated medical spas peddling bogus semaglutide, and have high-powered legal teams trying to stop them. Novo Nordisk has filed at least 21 lawsuits nationwide against companies making purported copies of its drugs, said Brianna Kelley, a spokesperson for the company, and urges doctors to avoid them. The FDA, too, has cautioned about the potential danger of the compounds, and leading obesity medicine groups starkly warn patients against their use.

But this isn't an illegal black market, though it has shades of gray.



OONA TEMPEST/KFF HEALTH NEWS

The FDA allows and even encourages compounding pharmacies to produce and sell copycats when a drug is in short supply, and the wildly popular GLP-1 drugs have enduring shortages — first reported in March 2022 for semaglutide and in December 2022 for tirzepatide. The drugs have registered unprecedented success in weight loss. They are also showing promise against heart, kidney and liver diseases and are being tested against conditions as diverse as Alzheimer's disease and drug addiction.

In recent years, the U.S. health care system has come to depend on compounding pharmacies, many of which are run as nonprofits, to plug supply holes of crucial drugs like cancer medicines cisplatin, methotrexate and 5-fluorouracil.

Most compounded drugs are old, cheap generics. Semaglutide and tirzepatide, on the other hand, are under patent and earn Novo Nordisk and Lilly billions of dollars a year. Sales of the diabetes and weight loss drugs this year made Novo Nordisk Europe's most valuable company and Lilly the world's biggest pharmaceutical company.

While the companies can't keep up with demand, they heatedly dispute the right of compounders to make and sell copies. Lilly spokesperson Kristiane Silva Bello said her company was "deeply concerned" about "serious health risks" from compounded drugs that "should not be on the market."

Yet marketed they are. Even Hims & Hers Health — the telemedicine prescriber that got its start with erectile dysfunction drugs — is now peddling compounded semaglutide. It ran ads for the drugs during NBA playoff games. (According to a Hunterbrook Media report, Hims & Hers' semaglutide supplier has faced legal scrutiny.)

The compounded forms are significantly cheaper than the branded drugs. Patients pay about \$100 to \$450 a month, compared with list prices of roughly \$1,000 to \$1,400 for Lilly and Novo Nordisk products.

Five compounders and distributors interviewed for this article said they conduct due diligence on every lot of semaglutide or tirzepatide they buy or produce, upholding standards of purity, sterility and consistency similar to those practiced in the commercial drug industry. Compounders operate under strict federal and state standards, they noted.

However, the raw materials used in the compounded forms may differ from those produced for Novo Nordisk and Lilly, said GLP-1 co-inventor Jens Juul Holst, of the University of Copenhagen, adding that care must be taken in drug production lest it cause potentially harmful immune reactions.

To date, according to FDA spokespeople, reports of side effects from taking compounded versions haven't raised major alarms. But everyone with knowledge of the industry, including the compounders themselves, worry that a single batch of a poorly made drug could kill or maim people and destroy confidence in their business.

"I liken the compounding industry to the airline industry," Mikhael said. "When you have an airline crash, it hurts everybody."

Warnings from the past

The industry endured just such a catastrophe in 2012, when the New England Compounding Center released a contaminated injectable steroid that killed at least 64 people and harmed hundreds more.

In response, Congress and the FDA had strengthened oversight. Mikhael's company is an outsourcing facility, or 503B compounding pharmacy — so-named for a section of the 2013 law that set new requirements for drug compounders. The companies are licensed to make slightly different versions of FDA-approved drugs in response to shortages or a patient's special needs.

The law created two classes of compounding pharmacies: The FDA regulates the larger 503B compounders with standards like commercial drug companies, while 503A pharmacies make smaller lots of drugs and are largely overseen by state boards of pharmacy.

The 503A facilities also are producing compounded semaglutide and tirzepatide for hundreds of thousands of patients. Like the 503Bs, these operations take the active ingredient, produced as a powder in FDA-registered factories, mostly in China, then reconstitute it with sterile water and an antimicrobial in small glass vials.

Together, the compounding pharmacies may account for up to 30% of the semaglutide sold in the U.S., Mikhael said, although he cautions that is a "wild ballpark figure" since no one, including the FDA, is tracking sales in the industry.

The compounders say the companies should increase production if they're worried about competition. Like the dozens of other drugs they produce for hospitals and medical practices, the compounders say, the two diet drugs are essential products.

"If you don't want a 503B facility to make a copy, it's pretty simple: Don't go short," said Lee Rosebush, chair of a trade association for 503B pharmacies. "FDA created this system because these are necessary drugs."

Novo Nordisk hasn't specified why it can't keep up with demand, but the bottleneck apparently lies in the company's inability to fill and sterilize enough of its special drug auto-injectors, said Evan Seigerman, a managing director at BMO Capital Markets.

The company announced June 24 that it was investing \$4.1 billion in new production lines at its Clayton, North Carolina, site. The FDA last year issued a warning over procedural violations at the site and separate cautions at an Indiana facility that Novo Nordisk took over recently.

Compounding for Dummies

At least 28 companies mostly in China, are registered with the FDA to produce or distribute semaglutide. At least half the companies have entered the market in the past 12 months, driving the raw material's price down by 35%, according to Scott Welch, who runs a 503A pharmacy in Arlington, Virginia.

Compounders can buy powdered semaglutide from some U.S. distributors for less than \$4,000 a gram, said Matthew Johnson, president and CEO of distributor Pharma Source Direct. That comes out to as little as \$10 per weekly 2.5-microgram dose.

While Ozempic or Wegovy patients use a Novo Nordisk device to inject the drug, patients using compounded products draw them from a vial with a small needle, like the device diabetics use for insulin.

Some medical practices provide the compounded drug to patients as part of a weight loss package, with markups. Last July, Tabitha Ries, a single mother of six who works as a home health care aide in Garfield, Washington, found an online clinic that charged her \$1,000 for three months of semaglutide along with counseling. She has lost 35 pounds.

She gets the drug from Mindful Weight Loss, a mostly telehealth-based operation led by physician Vivek Gupta of Manhattan Beach, California. Gupta said he's prescribed the weight loss drugs to 1,500 patients, with about 60% using compounded versions from a 503A pharmacy.

He hasn't seen any essential difference in patients using the branded and compounded forms, although "some people say the compounding is a little less effective," Gupta said.

There's some risk in using the non-FDA-approved product, he acknowledged, and he requires patients to sign an informed consent waiver.

"Nothing in life is without risk, but I would also argue that the status quo is not safe for people who need the medicine and can't get it," he said. "They're constantly triggered by all this food that's causing their weight to go up and their sugar to go high, increasing their insulin resistance and affecting their limbs and eyes."

Compounding semaglutide is a helpful sideline for pharmacists like him, Welch said, especially given the pinch on drug sale revenue that has led many independents to close in recent years. He figures he earns 95% of his revenue from compounding drugs, rather than traditional prescriptions.

It's important to distinguish compounded semaglutide from unregulated powders sold as "generic Ozempic" and the like, which may be contaminated or counterfeit, said FDA spokesperson Amanda Hils. But since compounded forms of the drug are not FDA-approved, those who make, prescribe or use them also should have "an increased level of responsibility or awareness," she said.

Corporate battles

Novo Nordisk and Lilly, in lawsuits each company has filed against competitors, say their own testing has found bacteria and other impurities in products made by compounding pharmacies. The companies also report patent infringement, but compounders, pointing to the FDA loophole for drugs in shortage, appear to have defeated that argument for now.

When the FDA removes the drugs from the shortage list, 503B compounders must immediately stop selling them. Smaller compounders may be able to produce their products for a reduced number of patients, said Scott Brunner, CEO of the Alliance for Pharmacy Compounding, which represents 503A compounders.

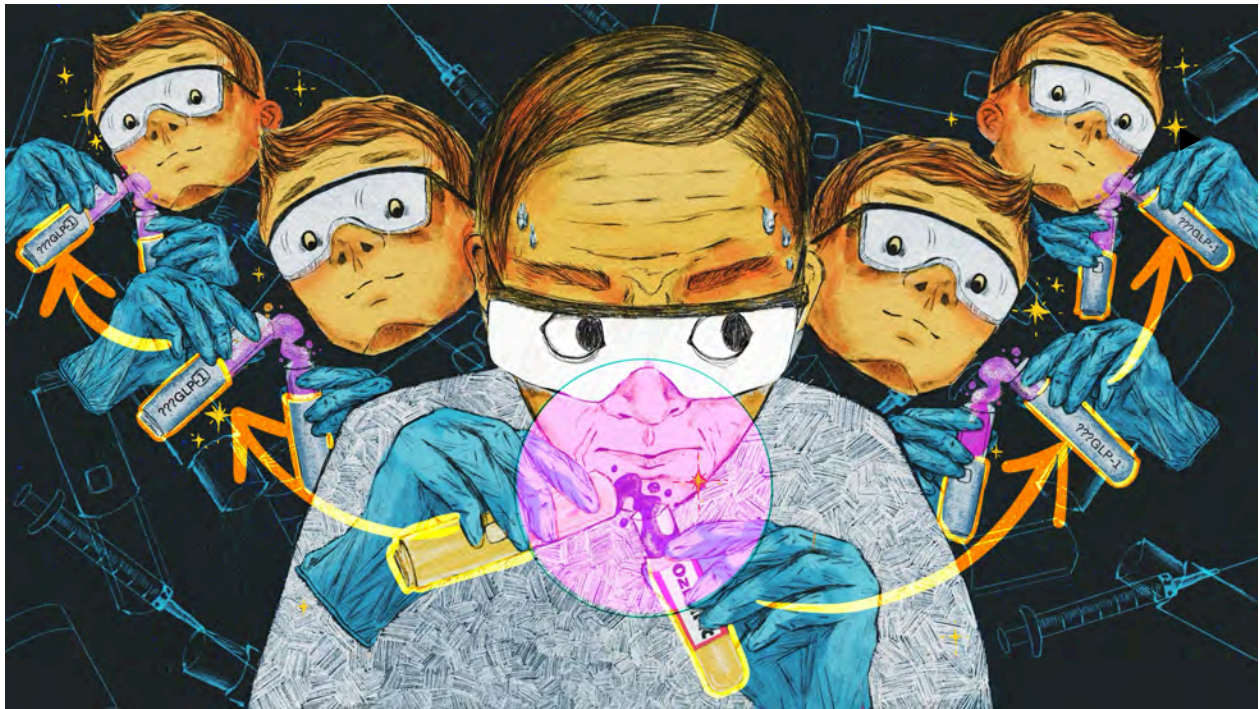
The evaporation of the compounded drug supply could come as a shock to patients.

"I dread it," said David Wertheimer, an internist in Franklin Lakes, New Jersey, who prescribes compounded semaglutide to some patients. "People are not going to be able to plunk down a grand every month. A lot of people will go off the drug, and that's a shame."

Exhibit 7

KFF Health News

Why Millions Are Trying FDA-Authorized Alternatives to Big Pharma's ...



(OONA TEMPEST/KFF HEALTH NEWS)

Why Millions Are Trying FDA-Authorized Alternatives to Big Pharma's Weight Loss Drugs

By Arthur Allen

Illustration by Oona Zenda

JULY 23, 2024

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CBS NEWS

This story also ran on [CBS News](#). It can be [republished for free](#).

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Arthur Allen: aallen@kff.org, [@ArthurAllen202](#)

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Exhibit 8

Copycat weight-loss drugs are major players with consumers

[washingtonpost.com/politics/2024/07/31/copycat-weight-loss-drugs-are-major-players-with-consumers](https://www.washingtonpost.com/politics/2024/07/31/copycat-weight-loss-drugs-are-major-players-with-consumers)

McKenzie Beard

July 31, 2024

Hello, I'm Arthur Allen. I write about the drug industry and related topics for KFF Health News. If you know of a neglected story in this area, send me a nudge at aallen@kff.org.

Compounding pharmacies' big stake in anti-obesity drugs

A surprising number of Americans aren't getting their weight loss drugs from pharma giants Novo Nordisk or Eli Lilly. (David J. Phillip/AP)

As many as **1 in 8** American adults has tried one of the GLP-1 anti-obesity drugs, but a surprising number aren't getting their supplies from pharma giants **Novo Nordisk** or **Eli Lilly**. Up to **30 percent** of the market, by some estimates, is made up of copycat versions from compounding pharmacies.

Compounding is legal, though the resulting products sometimes fall into a gray area because they're copies of drugs under patent and are not approved by the **Food and Drug Administration**.

Mark Mikhael, CEO of Orlando-based **Olympia Pharmaceuticals**, estimates that his and other large compounders provision up to **2 million** Americans each month with semaglutide, the scientific name for Novo Nordisk's Wegovy, Ozempic and Rybelsus formulations, or tirzepatide, the active ingredient in Eli Lilly's Zepbound and Mounjaro.

Many of the compounded drugs are produced for and sold by online pharmacies like **Hims & Hers Health**, **Henry Meds** and **Ro**. Others come from smaller compounding companies.

Novo Nordisk and Lilly fiercely oppose these sales and lump the compounders together with unregulated medical spas peddling bogus semaglutide. Novo Nordisk has filed at least **21 lawsuits** nationwide against companies making purported copies of its drugs, said **Brianna Kelley**, a spokesperson for the company, and urges doctors to avoid them.

When there's a drug shortage — the FDA has put semaglutide and tirzepatide on shortage lists since 2022 — the agency allows compounders to make it. The compounding companies get raw material for the drugs from mostly Chinese businesses that are registered and, at least in theory, inspected by the FDA.

Because the drugs are not strictly FDA-approved, those who make, prescribe or take them should exercise "an increased level of responsibility or awareness," FDA spokesperson **Amanda Hils** said.

But she distinguished the compounded drugs from unregulated powders sold as “generic Ozempic” and the like, which may be contaminated or counterfeit. The agency recently warned about patients taking the wrong doses of the compounds, but it hasn’t received a disproportionate number of side effect reports linked to these drugs.

Semaglutide and tirzepatide have registered unprecedented success in weight loss. They are also showing promise against heart, kidney and liver diseases, and are being tested to treat or prevent Alzheimer’s disease and drug addiction. It’s no wonder they are in shortage.

While most compounded drugs are copies of old, cheap generics, semaglutide and tirzepatide are under patent and earn Novo Nordisk and Lilly billions of dollars a year. Compounded forms are cheaper, particularly for patients whose insurers won’t cover the branded drugs.

While the pharmaceutical giants can’t keep up with demand, they dispute the right of compounders to make and sell copies. Lilly spokesperson **Kristiane Silva Bello** said her company was “deeply concerned” about “serious health risks” from compounded drugs that “should not be on the market.”

Mikhael’s company is an outsourcing facility, or 503B compounding pharmacy — regulated directly by the FDA. Smaller 503A pharmacies are largely overseen by state boards of pharmacy.

The compounders are defiant, calling the diabetes and diet drugs essential products.

“If you don’t want a 503B facility to make a copy, it’s pretty simple: Don’t go short,” said **Lee Rosebush**, chair of a trade association for 503B pharmacies. “FDA created this system because these are necessary drugs.”

KFF Health News is a national newsroom that produces in-depth journalism about health issues and is one of the core operating programs at KFF — an independent source of health policy research, polling and journalism.

White House prescriptions

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Health reads


Sugar rush

Exhibit 9

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r/Zepbound

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 **r/Zepbound** • 2 mo. ago
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Lilly CEO Says Weight-Loss Drug Will Be Off Shortage Soon


News/Information



Sorry, this post was deleted by the person who originally posted it.

 167 

 150

 Share

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allusednames • 2mo ago •

If you're having a hard time finding a dose, please make sure to report it to the FDA. What Lilly says and what people are experiencing seems to be two different things.

<https://cdernextgenportal.fda.gov/publicportal/s/dsm-submission>

 115 

 Reply

 Share



 19 more replies




Squeaker2160 • 2mo ago •

Let's see how long this lasts. If people start coming back from compound then the shortages will just start over again.

Part of the reason they are able to keep up with demand is because compounding pharmacies are supplementing.

 84 

 Reply

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 31 more replies




Timesurfer75 • 2mo ago •

Not sure I believe this. The two new plants are not going to be up to production until late 2025. But with this announcement their stock went back up. So, let's see how they plan on increasing available stock when there is no place to produce it.

 24 

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just stopped an order for my first round of 10mg because the pharmacy couldn't give me any idea when it might come in after a week. Had my doctor send a script for another month of 7.5 and had it within 2 hours

16 [Reply](#) [Share](#) ...



_lvmanda • 2mo ago •

I just tried to fill my 10mg at Costco earlier this week and their supplier is saying they won't have it until mid August... yet in early July I was able to fill it right away. So we'll see. That doesn't sound like wide open availability to me, either.

7 [Reply](#) [Share](#) ...



BigShaker1177 • 2mo ago •

I think shortages greatly depend on location, pharmacy and dosages.: I'm on 7.5 and have had zero issues from 2.5 to 5 to 7.5

11 [Reply](#) [Share](#) ...



External_Trick4479 • 2mo ago •

And pharmacy. CVS told me to just find a new pharmacy, that they couldn't order & Walmart said they don't have any issues for any dose 🙄

9 [Reply](#) [Share](#) ...

+ 2 more replies

+ 1 more reply



zepboundbabe • 2mo ago •

Anyone else notice in the stock photo they used that the gray cap is still on and the pen is locked? 🙄

10 [Reply](#) [Share](#) ...

+ 2 more replies



StraightGarage7054 • 2mo ago •

2 months ago the shortage will last well into 2025 or even 2026 but by some miracle the shortage is over . Complete BS. It's a money grab and or maybe Big pharma doesn't like the money they are losing due to the drug working

7 [Reply](#) [Share](#) ...



Mobile-Actuary-5283 • 2mo ago •

[Skip to main content](#)[Log In](#)https://m.youtube.com/watch?v=mr_kdkxYX5k

12 Reply Share ...

2 more replies

**theamp18** • 2mo ago •

yeah I was was to get my prescription in like 2 hours today

22 Reply Share ...

**Delco1000** • 2mo ago •

well you're on 5mg. Been waiting nearly 2 weeks for my 10mg to be filled.

21 Reply Share ...

11 more replies

**Inevitable-Shine-922** • 2mo ago •

I got 2.5, 5 & 7.5 all filled the day after my pharmacy (Walgreens) got the script. They told me I didn't need to fill my scripts 1-2 weeks early because they don't have any issues ordering! I am in SoCal!

10 Reply Share ...

2 more replies

**wonder_time_1110** • 2mo ago •

I'm in MI and I've been unable to get 10 or 12.5 for 9 weeks. I ended up getting a compound of 10 so that I wouldn't fall behind on dosage.

5 Reply Share ...

1 more reply

**Mobile-Actuary-5283** • 2mo ago •

But the CEO gave no details. Why not give details? Why not say SOMETHING specific?

I really hope this is accurate but I agree with [u/allusednames](#) -- what's out there and listed as available is not what many of us experience. I really wonder if the timing of this announcement coincides with the next quarterly earnings report ... nothing like dropping a nugget like this to news outlets to help drive up stock prices.





4 Reply Share ...

**External_Trick4479** • 2mo ago •

Their earnings call is next week. They'll address it.

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Now lower the price

 4   Reply  Share ...**houmi** • 2mo ago •

Walmart pretty much has same day availability... now I wish they would make the 550 cost lower...

 4   Reply  Share ...**Userofzep** • 2mo ago •

I was able to get 10 and 15 filled monday. Scrips had been in process over 5 weeks. I'm in Southern NH.

 3   Reply  Share ...**kangaruurunner** • 2mo ago •

I remember how COVID vaccine was in short supply. Then production went way up. It would not be surprising if Eli Lilly was able to expand manufacturing in view of the huge amount of money they can make by selling more of the drug.

 3   Reply  Share ...[View more comments](#)>>> [r/Zepbound](#)**A 4. Finally!!**

2.5K upvotes · 182 comments

>>> [r/Zepbound](#)**357-120**

1.7K upvotes · 204 comments



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1.2K upvotes · 53 comments

r/Zepbound

September Check in



1.1K upvotes · 65 comments

r/Zepbound

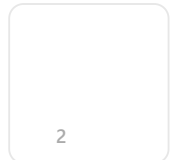
80 pounds down 🙌



1.1K upvotes · 72 comments

r/Zepbound

Down 100lbs thanks to Zepbound



1.1K upvotes · 59 comments

r/Zepbound

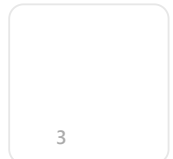
Goal... finally!!



1K upvotes · 76 comments

r/Zepbound

I never imagined I'd see this day



1K upvotes · 60 comments

r/Zepbound

95lbs gone



988 upvotes · 46 comments

r/Zepbound

Welcoming me back



901 upvotes · 62 comments

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non-alcoholic fatty liver. Last week I weighed in at 187.4, I no longer have issues with my liver, and I...

862 upvotes · 49 comments

r/Zepbound

Hit my target!

843 upvotes · 38 comments

r/Zepbound

117 days in

700 upvotes · 43 comments

r/Zepbound

5 months, 44 pounds down!

2

688 upvotes · 70 comments

r/Zepbound

Someone finally noticed!

682 upvotes · 44 comments

r/Zepbound

80lbs Down w/Zep

5

584 upvotes · 58 comments

r/Zepbound

Two years later.....

580 upvotes · 25 comments

r/Zepbound

finally lost 50!

3

570 upvotes · 36 comments



Log In

555 upvotes · 21 comments

r/Zepbound

Officially 30 lbs down!



555 upvotes · 21 comments

r/Zepbound

I can actually see it 🥹



553 upvotes · 30 comments

r/Zepbound

30lbs lost vs 80lbs lost



496 upvotes · 14 comments

r/Zepbound

8 Months 75 pounds down 🙏



492 upvotes · 25 comments

r/Zepbound

Face shot progress



491 upvotes · 64 comments

r/Zepbound

Ozempic came up in my fitness group thread - had to speak up 🗣️🗣️



459 upvotes · 83 comments

Exhibit 10



Obesity drugs

Zepbound shortages ease, but Lilly cautions pharmacy availability may remain ‘choppy’

Company CEO David Ricks said that, while product supply is flowing, all doses of the weight loss medicine may not be immediately available at drugstore counters.

Published Aug. 8, 2024



Delilah Alvarado
Staff Reporter

*Eli Lilly's logo is seen atop a company office building in San Diego, California.
JHVEPhoto via Getty Images*

Eli Lilly is making progress resolving the supply strains that for months have made its in-demand obesity and diabetes medicines difficult to get. However, even as shortages ease, the drugs' availability at the pharmacy counter may remain in flux.

Earlier this month, the Food and Drug Administration updated its drug shortage database to indicate that all doses of tirzepatide, which Lilly sells as Zepbound for obesity and Mounjaro for diabetes, were available. Previously certain dose strengths of both drugs had been listed as having limited accessibility.

“We’re available in all dosage forms in the U.S. What that means is we can bill orders as they’re received,” said Lilly CEO David Ricks on an earnings conference call Thursday. “That does not mean that any pharmacy, or certainly every pharmacy, has all 12 dosage forms sitting on their shelves.”

Ricks cautioned that, despite the change in status on the FDA's shortage list, patients may still have to wait a few days to pick up their prescriptions.

"There's not an abundance of supply. It's more of a real-time fulfillment situation," Ricks said. "But product is flowing and it's flowing at a pretty high rate."

Still, he added, "the end pharmacy experience will continue to be choppy."

Lilly has poured billions of dollars into expanding its manufacturing capacity, acquiring factories and most recently, committing to invest another \$5 billion in a manufacturing site in Lebanon, Indiana to ramp up production of tirzepatide.

That spending, which Lilly says is the largest investment in company history, is in response to the high demand for both Mounjaro and Zepbound. Even with supply shortages, sales of Mounjaro totaled \$3.1 billion in the second quarter, while Zepbound earned just over \$1.2 billion, Lilly said Thursday.

"[Prescription] volume is really high in this category and probably will end up being one of the highest volume categories in the history of the industry," said Ricks.

Lilly's manufacturing additions will take time to come online, however. In the meantime, the introduction of a new single-dose vial formulation for 2.5 milligram and 5 milligram Zepbound doses could help. "They certainly open up a node of the most constrained part of the supply chain," said Ricks, referring to the filling and finishing of final dose containers. "So it just adds to our capacity."

Competitor Novo Nordisk, which sells rival drugs Wegovy and Ozempic, has also faced supply constraints. Shares of the Danish drugmaker fell earlier this week after Wegovy sales failed to meet high expectations set out by Wall Street. Novo has also invested

into increased production capacity and, while most doses of its drugs are available, a starter Wegvoy dose is still listed as having limited availability, per the FDA.

Exhibit 11

POLITICO



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Prescription Pulse

Delivered every Tuesday and Friday by 12 p.m., Prescription Pulse examines the latest pharmaceutical news and policy.



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A 'mixed bag' for weight-loss drug supply

By **LAUREN GARDNER** and **DAVID LIM** | 08/06/2024 12:00 PM EDT

Presented by



DRIVING THE DAY

DEFINE 'AVAILABLE' — All dosage forms of Eli Lilly's popular GLP-1 drugs were considered "available" on the FDA's drug shortages database as of Friday, but the active ingredient underpinning the products is still listed as in shortage.

Pharmacists told Prescription Pulse on Monday that they still face obstacles ordering Mounjaro and Zepbound, Lilly's brands to treat diabetes and obesity, respectively. Availability depends on the wholesaler a pharmacy uses and which dosages they need.

That means patients nationwide aren't uniformly seeing more supply available just yet.

"It's kind of still a mixed bag," said a spokesperson for one major pharmacy chain who was granted anonymity to discuss a fluid situation.

Pharmacist Dave Miller, of Keystone Pharmacy in Grand Rapids, Michigan, said Cardinal Health's ordering platform on Monday showed that only three dosage forms were available for each drug. Even those marked available didn't necessarily have many to spare; Miller said the wholesaler only had two injectable pens in stock for some dosages.

Lilly "might have plenty in their warehouses, but it's not making it to the wholesaler level yet," he said.

That sporadic availability means doctors might hesitate to start prescribing GLP-1s to patients, pharmacists said, since they must start at a low dose and gradually build to see optimal results with minimal side effects.

"The supply chain is complex, especially for medicines that are temperature controlled, and there may be many reasons why a particular pharmacy does not have the medicine in stock," a Lilly spokesperson said in an email.

What does 'available' mean? The FDA considers several factors when moving a drug off the shortage list, even if "all dosages of a drug may currently be listed as available." The agency is still determining whether available supply meets its definition of a resolved shortage, spokesperson Amanda Hils said.

"FDA generally considers a shortage to be resolved ... based on an evaluation of the entire market, assessing whether all backorders have been filled and supply is meeting or exceeding demand," she said in an email.

The major pharmacy chain spokesperson said the manufacturer hasn't removed the backorder messaging from the wholesaler website, suggesting Lilly still isn't providing orders in full.

Why it matters: Compounding pharmacies can still legally make copies of the drugs for patients with valid prescriptions, which the FDA allows during a drug shortage.

"We're filling a lot of compounded GLP-1s at the moment, and it's growing on a monthly basis," said Jennifer Burch, who owns a compounding pharmacy and a retail pharmacy in Durham,

North Carolina. “We’re taking care of hundreds of patients.”

IT’S TUESDAY. WELCOME BACK TO PRESCRIPTION PULSE. Toddler-borne illnesses have given a whole new meaning to what Lauren considers “brat summer.”

Send tips to David Lim (dlim@politico.com or @davidalim) and Lauren Gardner (lgardner@politico.com or @Gardner_LM).

EYE ON THE FDA

BIPARTISAN PUSH FOR MDMA — The FDA is slated to decide by Sunday (in user fee tradition with a weekend deadline, likely Friday) whether to approve or deny a bid to market MDMA — commonly known as the party drug ecstasy — with talk therapy as a new treatment for post-traumatic stress disorder.

The application was the subject of negative FDA advisory committee votes earlier this summer, but that hasn’t stopped an unlikely grouping of Democratic and Republican lawmakers from advocating for the therapy’s approval, POLITICO’s Erin Schumaker reports.

We asked Erin to dive deeper into the bipartisan pressure campaign and the stakes of the agency’s decision:

The congressional push for MDMA approval is bipartisan. What were the common threads you found among the lawmakers advocating for this?

There’s a push from both sides of the aisle to do right by veterans with post-traumatic stress disorder. Some lawmakers, like Reps. Jack Bergman (R-Mich.), Jimmy Panetta (D-Calif.), Morgan Luttrell (R-Texas) and Dan Crenshaw (R-Texas), served in the military, while others, like Lou Correa (D-Calif.), didn’t serve but care deeply about veterans.

The optics aren’t great for Congress and the Department of Veterans Affairs: It’s been decades since there was a new PTSD treatment, and high suicide rates among veterans suggest the government isn’t doing enough to help them.

What do proponents fear will happen if Lykos’ application is denied? And what do the drug’s detractors warn could be a downside if it’s approved?

A green light from the FDA would have made life easier for psychedelics researchers and galvanized support for their work. A “no” will likely give those researchers pause. Research won’t grind to a halt, but it won’t speed up, either.

Detractors worry that if the agency approves Lykos Therapeutics’ regimen — despite concerns from the advisory committee that the therapy isn’t effective and that its risks outweigh its

benefits — patients could be harmed.

If the FDA denies the application, what's next for psychedelics research and its champions in Congress?

It's not the end of the road, members told me.

The VA and the National Institutes of Health will continue doing psychedelics studies, and the Congressional Psychedelics Advancing Therapies Caucus and its allies in Congress will keep pushing for FDA approval.

As Crenshaw said: "If they don't approve this one, I think it just provides a better roadmap for the next one."

DRUG PRICING

PETITION FOR GENERIC WEIGHT-LOSS DRUGS — Consumer advocacy group Public Citizen is petitioning HHS to use its patent power to allow Medicare, Medicaid and other federal programs to buy generic copies of popular weight-loss drugs like Ozempic.

The group argues that the authority — also known as section 1498 — allows the government "to make use of patented inventions in exchange for paying reasonable compensation to the patent holder."

"Pursuant to the terms of § 1498, Novo Nordisk would not be able to obtain injunctive relief to prevent these firms from supplying these federal programs; its only remedy would be reasonable compensation as determined by a court," Public Citizen's petition states. "The savings introduced by generic competition would significantly outweigh any reasonable royalty rate that a court would set in these circumstances."

PHARMA MOVES

The **National Association of Chain Drug Stores** has named **Stephanie Katz** as vice president of reimbursement, innovation and advocacy. She most recently served as assistant vice president for policy and advocacy at the National Council for Mental Wellbeing.

WHAT WE'RE READING

Limits on the amount of financial rewards federal programs can give to those who reduce or stop meth use obstruct the government's efforts to combat the fight against substance use disorder, STAT's Lev Facher reports.

Research published in JAMA Network Open showed that some semaglutide products sold by illegal online pharmacies contained more of the ingredient than the labeled amount and that they could possibly be contaminated.

DOCUMENT DRAWER

Several FDA staff — including FDA Commissioner Robert Califf — met with members of drug lobby PhRMA on July 22 to discuss “vaccine review challenges and combating misinformation,” according to a new public calendar disclosure.

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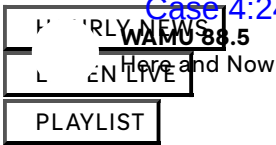
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Exhibit 12

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AMERICAN UNIVERSITY RADIO

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Shots

SHOTS - HEALTH NEWS

Drugmakers say obesity medicine shortages are easing, but patients struggle to fill prescriptions

SEPTEMBER 6, 2024 · 11:57 AM ET

By Sydney Lupkin

3-Minute Listen

PLAYLIST

Download

Transcript



Surging demand for new medicines to treat obesity and diabetes make it hard for many patients to get them.

Michael Siluk/Getty Images

Bill Coombs, who lives in Boston's South End, has lost 28 pounds since he started using the obesity drug Wegovy.

But when he went to refill his prescription in late August, things didn't go as planned.



SHOTS - HEALTH NEWS

Torrid market for copycat weight loss drugs could be short-lived

"I take it every Wednesday. So this Monday my prescription was up," he says. "So I called to fill my prescription, and they said, 'You're fine.' When I went in ... to get it, they said they're out and they're going to be out for the foreseeable future."

He'd been worried about missing doses of the drug after a friend had similar trouble.

Then, somehow, the pharmacist found some Wegovy, but Coombs doesn't know how.

"I did end up getting it, which is fortunate, but I do worry about it," he says. "I do worry about what's going to happen in a month."

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5 best practices to reduce fraud

The massive popularity of Ozempic, Wegovy, Mounjaro and Zepbound has meant the drugs have been in and out of short supply for more than a year, as the drugs' makers have been struggling to keep up with skyrocketing demand.

Novo Nordisk and Eli Lilly are the pharmaceutical companies that make the popular medications for diabetes and obesity. They recently said that their drugs are “available” again with the exception of the starting dose of Novo Nordisk’s Wegovy.

But patients like Coombs are still having trouble at the pharmacy counter.

Drugs remain hard to get

David Knapp takes Lilly’s Mounjaro for his Type 2 diabetes and has a podcast, blog and YouTube channel called *On the Pen*. Patients taking the drugs reach out to him every week to share their experiences coping with shortages.

“They’re doing the tricks, right? All the tricks,” he says. “They’re going up a dose. They’re moving back a dose. Some people I’ve heard calling 100 pharmacies in their state, just trying to find their dose.”



SHOTS - HEALTH NEWS

Ozempic's popularity leads to shortages for people with Type 2 diabetes

He says many patients took offense at drugmakers’ declarations that the injections are available again.

And the Food and Drug Administration has kept the drugs on its official shortage list. The agency says it needs to be sure the drug companies can meet demand. That includes verifying the manufacturers have a supply cushion of the drugs and that the companies have fulfilled all their backorders.

It’s not clear how long the process will take.

Pharmacies out of stock

Right now, pharmacists can’t be sure they’ll get their full orders from drug wholesalers, says Erin Fox, who tracks drug shortages as part of the American Society of Health-System Pharmacists.

Sponsor Message

“That can mean that if you might order 20, but you might only get 10,” she explains.

When wholesalers allocate their drug supplies like that, she says it usually means there isn’t enough of the drug to go around.

The supply chain is complex for refrigerated medicines like Mounjaro and Zepbound, Eli Lilly spokesperson Rachel Sorvig wrote in an email to NPR.

“There may be many reasons why a particular pharmacy does not have a particular dose of the medicine in stock,” Sorvig says. “Lilly recommends that patients contact their pharmacy approximately one week before the medicine is needed to start the prescription refill process sooner.”

Novo Nordisk spokesperson Jamie Bennett told NPR the company can’t control which pharmacies or patients get Ozempic in the U.S. The company is limiting how much of the starting dose of Wegovy it produces to focus on supplying the drug to patients already on it and who work their way up to higher doses for continuing treatment.

Signs the shortage is easing

The drug companies are spending billions of dollars building new factories and expanding production.

Novo Nordisk told investors in August that it has been able to double U.S. Wegovy prescriptions this year.

“While demand is still expected to exceed supply, we grow more confident in our ability to supply,” Novo Nordisk Executive Vice President of North America

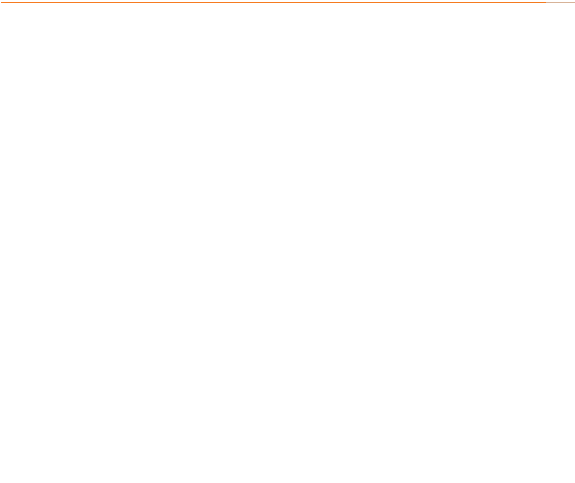
For Lilly’s part, the company tells NPR its factories that make these drugs are running 24 hours a day, seven days a week, 365 days a year.

Drug samples make a comeback

Pharmaceutical sales reps continued visiting doctors’ offices despite the shortages, but they stopped bringing free samples with them, says Dr. Scott Isaacs, the president-elect of the American Association of Clinical Endocrinology.

One sign the shortages may be easing? The samples are back.

Sponsor Message



“They're in our office frequently,” Isaacs says of the sales reps. “They're bringing samples. They're bringing brochures. And they're telling us that there are no shortages.”

The shift has made him optimistic about the drug supply.

“It does encourage me to write prescriptions for medications that I was previously not — because I knew the patient wouldn't be able to get the medication,” he says. “But unfortunately, sometimes you still write the prescription, and the patient still can't get the prescription.”

wegovy ozempic zepbound mounjaro drug shortages



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Exhibit 13



Ro > Weight loss > GLP-1 >

Zepbound availability: how do you find Zepbound?



Reviewed by [Patricia Weiser, PharmD](#),

Written by [Amelia Willson](#)

LAST UPDATED: SEP 10, 2024 6 MIN READ

Key takeaways

- Drug shortages have affected Zepbound on and off since spring 2024.
- At the time of publication, all dosage strengths of Zepbound are listed as available and should be in stock.
- During a Zepbound shortage, consider ordering your refill earlier than normal, requesting a 2- or 3-month supply, or contacting other local and online pharmacies to see if they have Zepbound in stock.
- You can also talk to your healthcare provider about Zepbound alternatives, including other injectable GLP-1 medications or prescription weight loss pills.

HERE'S WHAT WE'LL COVER

01 Is Zepbound available?

02 When will Zepbound be available?

03 How can I find Zepbound in stock near me?

Zepbound (tirzepatide) is an injectable prescription medication for weight loss indicated for people with obesity or overweight and designed to be used in combination with diet and exercise. Zepbound shares the same active ingredient and dosage strengths as Mounjaro, a medication for type 2 diabetes that may be prescribed off-label for weight loss.

Both drugs have been affected by long-term drug shortages. The demand for Zepbound, Mounjaro, and GLP-1 agonists drugs, such as Wegovy (semaglutide), Ozempic (semaglutide), and Saxenda (liraglutide), continues to outpace supply. At the time of writing, however, all of the dosage strengths of Zepbound are available.

Read on as we share the latest on Zepbound's availability and offer advice for finding Zepbound in stock near you.

Zepbound Important Safety Information: [Read more about serious warnings and safety info.](#)

Mounjaro Important Safety Information: [Read more about serious warnings and safety info.](#)

Wegovy Important Safety Information: [Read more about serious warnings and safety info.](#)

Ozempic Important Safety Information: [Read more about serious warnings and safety info.](#)

Saxenda Important Safety Information: [Read more about serious warnings and safety info.](#)

Weight loss

Get Zepbound

Lose up to 20% body weight in a year, if prescribed.

Get started

Weight loss claims apply to branded medications. Limited availability of some doses of Zepbound. See [Important Safety Information](#)



Is Zepbound available?

At the time of publication, tirzepatide (the active ingredient in Zepbound) is categorized as “currently in shortage” while the individual dosage strengths of Zepbound are listed as available, according to the Drug Shortages website managed by the US Food and Drug Administration (FDA). Meaning, you should

be able to find the following strengths of Zepbound in stock at your local pharmacy: 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg.

The same is true for Mounjaro, which also contains tirzepatide as the active ingredient and comes in the same dosage strengths. Both Mounjaro and Zepbound are manufactured and produced by Eli Lilly. As for where they differ? Their FDA-approved indications.

- Zepbound is intended for people with obesity and overweight and helps with weight loss and weight management when taken in combination with a reduced-calorie diet and increased physical activity.
- Mounjaro is intended for people with type 2 diabetes and helps lower blood sugar levels when used in combination with diet and exercise.

Both Zepbound and Mounjaro have experienced shortages in the past. More specifically, Zepbound has been on and off the FDA's Drug Shortages list since April 2024 while Mounjaro has done stints on the list since 2022. The increase in Zepbound's availability comes after a months-long shortage of the drug, which Eli Lilly attributed to "unprecedented demand" for Zepbound. And while it seems that the manufacturer might have gotten a hold on this issue, during an early 2024 investor call, Eli Lilly acknowledged that it expects demand to outpace supply through the rest of this year. Meaning, patients might face problems finding Zepbound in stock again before the ball drops in December. During the investor call, the company also announced that it plans to produce 1.5 times as many doses of Zepbound in the second half of this year as it did in the second half of 2023.

In order to achieve such a goal and catch up with demand, Eli Lilly has been working to expand their global manufacturing and supply chain. In June 2024, for example, the manufacturer opened a new plant in North Carolina; it also plans on building additional new facilities (such as one in Germany) in the coming years and expanding manufacturing capacity at some sites. Even so, the drug maker expects demand to continue to outpace supply throughout 2024.

In addition to the sky-high demand for the weight loss drug, the injector pen it comes in is yet another factor contributing to the vacillating availability of Zepbound shortage. Zepbound is administered via a once-weekly injection. Each box of Zepbound includes four pre-filled pens, each containing a single dose of the medication. According to David Ricks, the CEO of Eli Lilly, producing these pens is one of the "most complex [processes] on the planet," further contributing to and exacerbating the shortage.

When will Zepbound be available?

As mentioned above, all dosage strengths of Zepbound are currently available at the time of publication. That being said, to get a better idea of Zepbound's availability, you can search for "tirzepatide" on the FDA Drug Shortages website. You can also sign up for supply update emails on the LillyDirect website (make sure that "Lilly medicines/supply updates" is checked when you subscribe) as well as through the Ro GLP-1 Supply Tracker—but more on that below.

How can I find Zepbound in stock near me?

As you may already know, trying to fill your prescription of Zepbound can be frustrating, and this is especially true during a shortage. Below, we share seven tips for finding Zepbound in stock near you.

1. Follow up with your pharmacy

During a Zepbound shortage, your pharmacy's supply can be unpredictable. If your pharmacy is out of stock, [Eli Lilly](#) recommends continuing to check in with them over the next 2-10 days as their stock can change day to day and prescriptions can continue to be filled, just with a delay. You can also check the status of your prescription on the pharmacy's website or app.

2. Contact other local pharmacies

If you're struggling to fill your prescription, it might be because your pharmacy is out of stock of Zepbound. But that doesn't mean that other pharmacies are also dealing with a depleted supply of the drug. So, try calling around to see if other pharmacies in your area have Zepbound in stock. If they do, you may be able to transfer your prescription. Also, be aware that some pharmacies don't actively keep Zepbound in stock, but they can try to order it if you have your Rx for Zepbound sent there.

Pro tip: When calling, be sure to ask about your specific dosage strength. During a shortage, pharmacies may have some doses in stock but not others.

3. Order refills earlier than normal

To avoid a delay in filling your prescription, it's a good idea to order your refill much earlier than you normally would. This may help you get ahead of the delays that typically occur during a Zepbound shortage.

4. Request 3-month supplies

Zepbound is available in 1-, 2-, and 3-month supplies. If you've been filling your prescription on a month-to-month basis, ask your pharmacist about a 3-month supply instead. Having access to a longer supply may help you avoid any gaps in your treatment plan, especially if a Zepbound shortage occurs.

If you are taking advantage of the [Zepbound Savings Card program](#) to lower the [cost of Zepbound](#), the 2- and 3-month supplies are [eligible](#) for the program as well.

5. Try online fulfillment options

If you can't find Zepbound in stock near you, go online. Online pharmacies like Amazon Pharmacy and others may have Zepbound in stock. Eli Lilly also offers home delivery of Zepbound through their

LillyDirect Pharmacy Solutions program. Conveniently, many online pharmacies also offer free home shipping.

Online weight loss programs, such as Ro, may offer prescriptions for Zepbound or other weight loss medications (if appropriate). In addition, Ro offers a personalized coaching regimen that helps you keep up with the lifestyle changes recommended when taking Zepbound, such as diet and exercise, as well as help with getting insurance coverage.

6. Get help from online communities and tools

Free and accessible to all, the Ro GLP-1 Supply Tracker helps patients (and providers!) stay informed about the latest drug shortages. Through the tool, you can report shortages to the FDA, track which drugs are currently in short supply (according to the FDA and community reports), as well as receive updates when supply becomes available nearby.

You can also monitor Zepbound availability near you by joining the r/Zepbound subreddit on Reddit. At the time of writing, the community boasts 64,000 members. There are many threads about Zepbound availability—so many, in fact, that the moderators have instituted a “Weekly Availability Discussion” thread. Each week, users share pharmacies where they were able to find Zepbound and in what dosage strength so others can find it, too. There are even regional chat rooms that make it easier to find Zepbound in stock.

Plus, the community is a great place to connect with other Zepbound users to ask questions and get support.

7. Consider Zepbound alternatives

During a drug shortage, some health providers may recommend switching to a different drug to avoid any disruptions in treatment. Some health providers may recommend switching to Mounjaro, which contains the same active ingredient as Zepbound but is FDA-approved for type 2 diabetes, or they may recommend switching to another medication altogether, such as another GLP-1 injectable medication for weight loss or a weight loss pill.

Zepbound alternatives for weight loss include:

- Wegovy (semaglutide)
- Saxenda (liraglutide)
- Qsymia (phentermine/topiramate)
- Contrave (naltrexone/bupropion)
- Xenical (orlistat)
- Alli (orlistat)

Similar to Zepbound, Wegovy and Saxenda are both injectable medications that are FDA-approved for weight loss. However, at the time of writing, one or more dosage strengths of Wegovy and Saxenda are experiencing limited availability without a projected end date, according to the FDA.

The other Zepbound alternatives listed—Qsymia, Contrave, Xenical, and Alli—are all oral medications you can take for weight loss. At the time of writing, none of these medications are in shortage, according to the FDA Drug Shortages website.

Drug shortages can be an unwelcome surprise, to say the least, but you have options for finding Zepbound. Plan ahead for refills, explore local and online pharmacies near you, and talk to your healthcare provider about your concerns.

DISCLAIMER

If you have any medical questions or concerns, please talk to your healthcare provider. The articles on Health Guide are underpinned by peer-reviewed research and information drawn from medical societies and governmental agencies. However, they are not a substitute for professional medical advice, diagnosis, or treatment.

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Current version

September 10, 2024

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Fact checked by

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Patricia Weiser, PharmD, is a licensed pharmacist, health content writer, and medical reviewer with more than a decade of clinical experience in community and hospital pharmacy.

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included**

Provider

consultation

GLP-1

prescription

(if

appropriate)

Insurance

concierge

Ongoing

care &

support

Tools to

track

progress

Get
started

Learn
more
about
pricing

Please note: The
cost of medication
is not included in
the Body
membership.

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Erectile

FAQ

Dysfunction



Ozempic	Ro	Returns	Consumer	2024 ©
Wegovy	Operating& System	Health Data	All rights reserved, Ro	
Zepbound	Advisors	Pricing	Your Privacy	x
Cialis	Careers	GLP-1	Choices	
Hair Loss	Press	Supply Tracker		
	Health Guide	GLP-1 Insurance		
	Blog	Checker		

Exhibit 14



Ro > Corporate Blog >

Taking Stock: What Ro's GLP-1 Supply Tracker Reveals about the Drug Shortages

Written by Ro

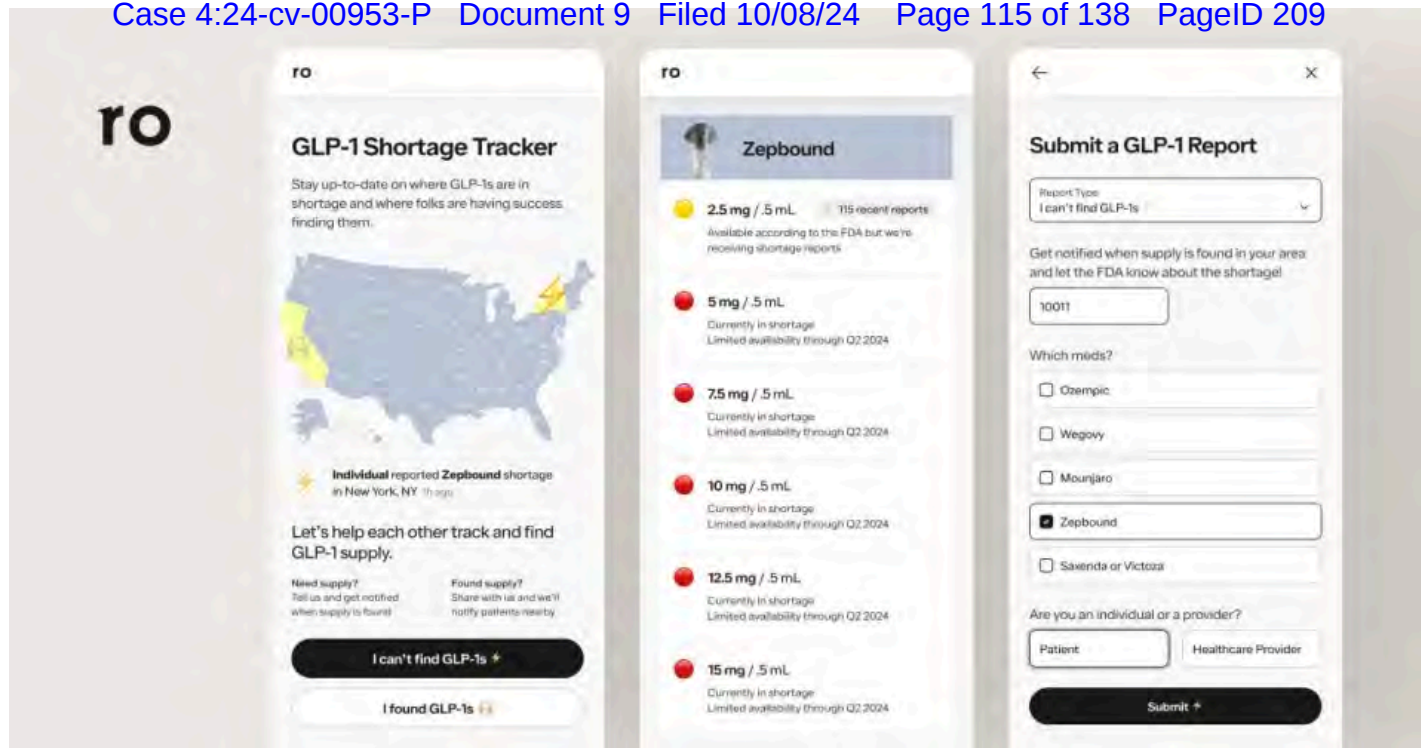
LAST UPDATED: OCT 03, 2024 4 MIN READ

HERE'S WHAT WE'LL COVER

- 01 What we know from patients
- 02 Pharmacy supply insights
- 03 Updates from pharmaceutical companies
- 04 The FDA's Drug Shortage List
- 05 Could things be improving?

10/3/24 update – Analyzing September shortage reports, more than one in 5 shortage submissions (over 22%) last month were for tirzepatide.

...



9/4/24 – Drug shortages continue to be a major hurdle preventing tens of millions of patients from starting or continuing their GLP-1 treatment. And the lack of accurate, up-to-date and easily accessible information on drug availability has made these shortages even harder to navigate.

That's exactly why we launched the GLP-1 Supply Tracker. This free, open-access tool gives patients real-time insights on GLP-1 drug shortages and lets them sign-up for automated, localized supply alerts (more on how it works).

In the months since we launched the GLP-1 Supply Tracker, there's been ongoing news and updates about the GLP-1 shortages. What matters most though is **what patients are experiencing** – are they able to reliably access their medication? Right now, the evidence suggests not.

What we know from patients

Since introducing our tool 3 months ago, patients have submitted **over 60,000 shortage reports** and we continue to receive thousands of reports each week.

- **Wegovy and Zepbound are the most reported medications:**
 - **45%** of all shortage reports are for Wegovy
 - **34%** of all shortage reports are for Zepbound
 - **19%** of all shortage reports are for Ozempic and Mounjaro, GLP-1s indicated for type-2 diabetes
- **Starter doses are the most often reported:**

- **Wegovy 0.25mg** is the most commonly reported dosage, appearing in about twice as many reports as other Wegovy doses.
- **Zepbound 2.5mg** is the most frequently reported dose of the drug.

Additionally, patients – whether Ro's or those simply using our GLP-1 Supply Tracker to find their medication – have shared feedback about their difficulties finding supply of their medication. The quotes below are a sample of what we heard when automated alerts from our tracker notified patients about the FDA changing the availability status of certain Mounjaro and Zepbound doses in August. What's clear from what we have heard from patients is that there is good reason for these drugs to still be on the shortage list. Even for doses marked 'available', patients are still not reliably accessing supply from their pharmacies.

"I cannot find any pharmacy with Zepbound 12.5 available...I have tried 8 different zip code areas."

"I am going on 3 weeks without being able to get a refill on Mounjaro 12.5...That is far from available in my opinion."

"I'm not certain how you get your information, but I can assure you it is inaccurate. Zepbound 12.5 & 15 have been out of stock since the beginning of July. I have checked with 20 stores near me."

"Locally I am being told that 10,12.5 and 15 are not and does not look like they will be available for the foreseeable future. How can Eli Lilly lie about the availability of the drug just to get congress to stop the manufacturing of the compound? It is wrong for them to do this."

"I have been seeing availability for Mounjaro 12.5 however I've not been able to secure any since June! Called around to numerous pharmacies today and still not available!"

Pharmacy supply insights

A drug wholesaler who Ro works with saw supply of GLP-1s begin to increase in July, but said that it remained difficult to maintain enough inventory to meet patient demand. The wholesaler shared that certain doses of medications continue to intermittently go out of stock.

- **Only one dose of Wegovy (2.4 mg), was consistently in stock over the past 8 weeks.**
 - Wegovy 0.5mg was out of stock in 4 of the last 8 weeks.
- **The lower doses of Zepbound (2.5 mg and 5 mg) as well as the highest dose (15 mg) were consistently in stock over the past 8 weeks.**
 - Zepbound 10 mg and 12 mg were out of stock in 4 of the last 8 weeks.
- **All doses of Ozempic were in stock throughout the past 8 weeks.**

- Three middle doses of Mounjaro (7.5 mg, 10 mg, and 12 mg) were out of stock at least one of the past 8 weeks.

Updates from pharmaceutical companies

Recently, Novo Nordisk and Eli Lilly have expressed increased belief in their ability to increase supplies of their GLP-1 medications, but have acknowledged that some patients will still experience shortages. Novo Nordisk noted during the company's earnings call on August 7 that demand is still expected to surpass supply, but the company is continuing to focus on expanding supply so more patients can access its medications. Similarly, Eli Lilly highlighted on August 8 that progress on supply has bolstered their outlook, but that "the end pharmacy experience will continue to be choppy."

The FDA's Drug Shortage List

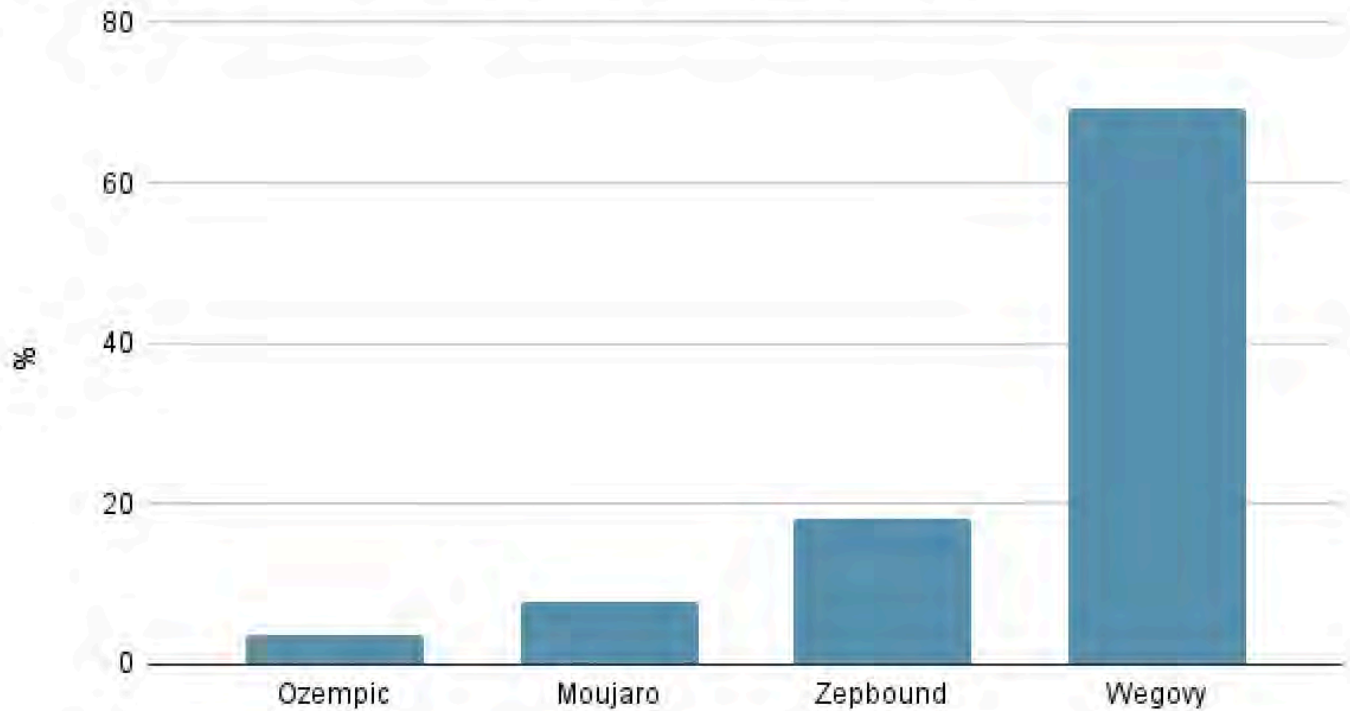
The GLP-1 shortage began in March 2022, with semaglutide injection (the active pharmaceutical ingredient in Ozempic and Wegovy) first appearing on the FDA's shortage list, followed by tirzepatide injection (the active pharmaceutical ingredient in Mounjaro and Zepbound) in December 2022. In August, all Wegovy doses except for 0.25mg and all doses of Ozempic, Zepbound, and Mounjaro were marked "available" according to the FDA's list. Importantly though, the FDA still lists both semaglutide and tirzepatide injections as "Currently in Shortage" – its designation that there is a drug shortage and the drug is not commercially available.

The agency recently explained that it considers the bigger picture in determining when a drug should be on its shortage list, saying, "FDA generally considers a shortage to be resolved ... based on an evaluation of the entire market, assessing whether all backorders have been filled and supply is meeting or exceeding demand."

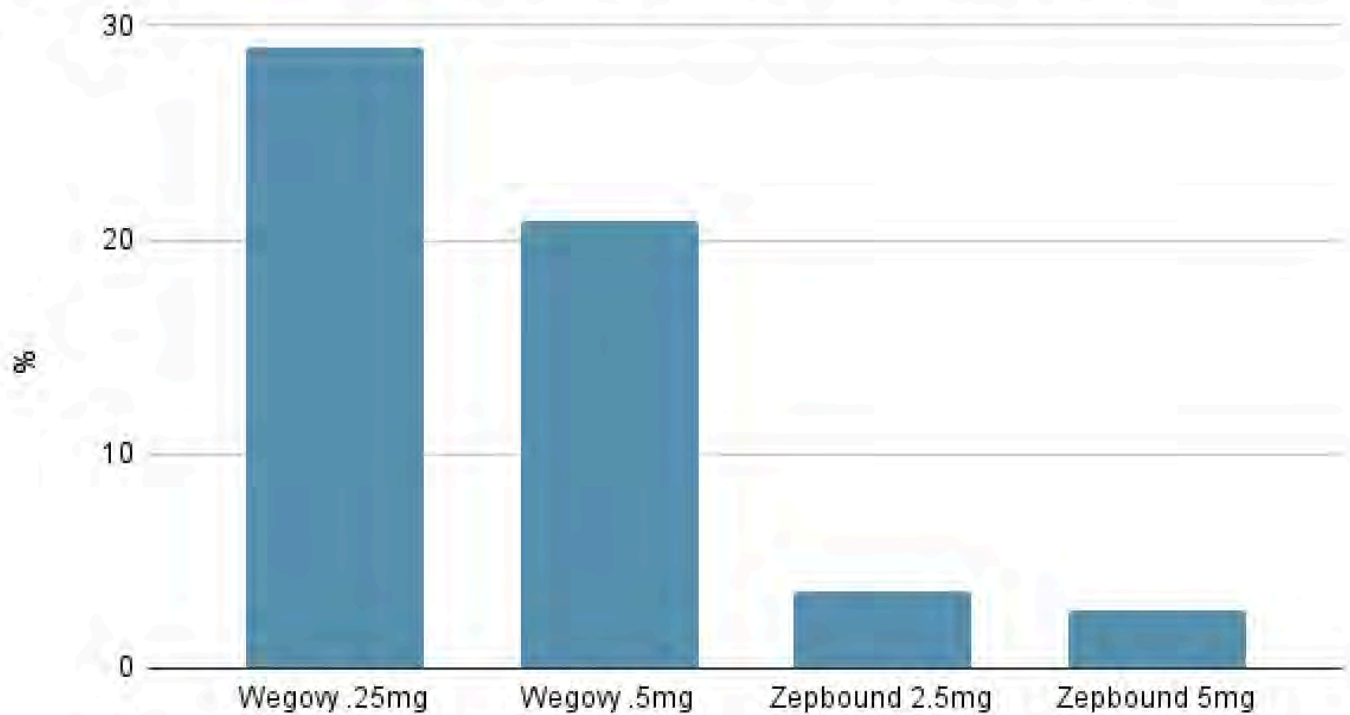
Could things be improving?

While evidence demonstrates that drug shortages have been persistent and continue affecting patients, there are some signs of supply progress among some GLP-1s medications. In August, Zepbound only accounted for ~18% of all shortage reports to our GLP-1 Supply Tracker. Similarly, while the starter doses of Wegovy, 0.25mg and 0.5mg, accounted for 29% and 21% of shortage reports respectively in August, the lower doses of Zepbound, 2.5mg and 5mg, accounted for less than 4% and 3% respectively.

Percentage of Shortage Reports by Medication



Percentage of Shortage Reports by Specific Medication Doses



Navigating the shortage is hard, but finding GLP-1s shouldn't be. Ro is proud that our tracker, and other free tools that we've built, such as the [GLP-1 Insurance Checker](#), are helping patients navigate their GLP-1 journey. However, we know there is more to do. There are currently 5-10 million people on a branded GLP-1 medication, but there is an estimated 50-60 million who are clinically eligible to receive Wegovy

and have insurance coverage for it, and of those, millions could purchase it for a copay of less than \$100/month. That is a lot of unmet demand that supply still must meet.

At Ro, we are rooting for the shortages to end as quickly as possible so that every single patient who could benefit from a GLP-1 medication has full, uninterrupted access. In the meantime, we'll continue to fight for patients every single day: helping ensure continuity of care for those already on GLP-1s and enabling new patients to start the most effective treatment available.

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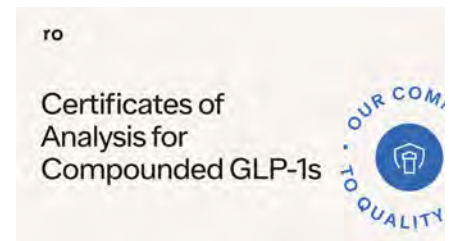
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Commitment to Quality: Ro's Certificates of Analysis for Compounded GLP-1s



Exhibit 15

[r/Zepbound](#) • 2 mo. ago[puddlesforoceans](#)

No more supply shortage.... But....

Rant

Saw that Lilly announced that all doses are now available and there is no more shortage on the news.

Well... Lilly DIRECT. Where's my 10mg?!? I've been on 7.5 for months this script has been sitting there withering away lol.

Zepbound™ 10 MG/0.5ML Solution Auto-injector

Generic: tirzepatide



MANUFACTURER SAVINGS

Medication out of stock

This medication is currently out of stock. Please check back soon.



Restock Notifications **ON**

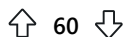
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60



59



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**RedTrainChris** • 2mo ago •

Send to FDA



35



Reply

**CarlosHDanger** • 2mo ago •

Report shortages to the FDA. Here is the link:

<https://cdernextgenportal.fda.gov/publicportal/s/dsm-submission>

22



Reply

**allusednames** • 2mo ago •

It was last in stock on July 11th.



7



Reply

**Dense_Target2560** • 2mo ago • Edited 2mo ago •

Consider checking a smaller, local pharmacy, or one affiliated with your local hospital. I've had incredible success with this resource, even when 15mg was officially on the FDA shortage list, while all the rest (larger chains) have had supply issues. This last month, it wasn't in stock when the script was sent over at 4pm Wednesday, but they placed an order & it was ready to be picked up on Thursday morning.



6



Reply

**pMedium5643** • 2mo ago •

FYI - CVS only uses 1 vendor that's why they never have anything. I went to a mom & pop shop & got 12.5mg & 15mg. They work with several vendors. I called every large pharmacy out there & this mom pop could get most of the doses. Happy Zepping!



5



Reply

**No-Personality-222** • 2mo ago •

I know it's hard to find the boxes, but I always have. Granted, I have to call somewhere between 15-20 Walmart/Sams/Costco pharmacies, some as far as 50 miles away, but I've always filled the earliest day my insurance allows. I live in Houston and to get my first 10mg I drove to Dallas because they had 3 boxes at this one Walmart. Every other time I've found them in a 50 mile radius. Idgaf, I'll get my box come hell or high water.



4



Reply

**puddlesforoceans** OP • 2mo ago •



6 Reply ...

1 more reply

**Timesurfer75** • 2mo ago •

You all realize that the reason EL came out and said that they were no longer going to report any shortages to the FDA was so that soon the government will no longer allow compounds to be made? It has nothing to do with hey, all of a sudden, we have Zepbound from production plants that are barely off the ground and in no way can be producing the drug? There are no drugs coming people. It is their ploy to stop allowing people to get the compounds. EL even said during their last investors call that it would not be until late 2025 that we would see any relief from the current situation. We will see next week what they have to say about all this when the next investors call is due. Unless they have decided to release the vials there is no way that their production plants can make more drugs since only one has been built and the other two are in the process of being built.

8 Reply ...

**CarlosHDanger** • 2mo ago • Edited 2mo ago •

Thank you. This is it exactly. And when the compounders are driven out of business that is when the real shortages begin.

Please report your failed attempts to buy Zepbound and Mounjaro to the FDA. Also Ro has a tracker that you can use to report shortages.

<https://cdernextgenportal.fda.gov/publicportal/s/dsm-submission>

4 Reply ...

1 more reply

1 more reply

**RavenZZees** • 2mo ago •

It seems like it just depends on the store. I filled 10mg about 2 weeks ago at Walmart and the fridge was stocked with all types of GLPs and dosages.

3 Reply ...

2 more replies

**kevink4** • 2mo ago •

So all the actual doses are available. Not everywhere, but somewhere.

A couple weeks ago I was at walmart, and Corn on the cob was out of stock. It happens.

Unfortunately, we still aren't to the point yet that anyone who wants a box of Zepbound can find it easy at their pharmacy.

As for Truepill, the 2 dosages I have active subscriptions for are showing as available. 2.5 and 5. But now that I have insurance approval for Zepbound, I can't get coverage at Truepill because they are out of network for me. I just hope that the local Walmart will have it in stock later in the week when it is time to refill.

↑ 7 ↓ [Reply](#) ...



RadioRob-DC • 2mo ago •

I am moving to 7.5 next weekend. My local CVS says there are 6 people waiting in front of me for it and they don't know when they'll have it. Walgreens basically laughed at me and had zero clue. I happened to be at Publix across the street and asked at the pharmacy there.

The pharmacist said they did not have any this weekend, but another store nearby had it and could get it transferred for me on Monday or Tuesday. Since I don't need it until Saturday, that's the plan for me!

↑ 5 ↓ [Reply](#) ...

[+](#) 7 more replies



programming_potter • 2mo ago •

FWIW I am on pain meds, one that is not widely prescribed. Only one of my local pharmacies can get it, the others say it's back ordered. This med is not in shortage. I don't know why some stores can get it and others can't but a medication not being in shortage doesn't mean it's easily available. Note: I didn't invent this!

⊖ ↑ 3 ↓ [Reply](#) ...



Accurate-Ad-5339 • 2mo ago •

You're right. I also think it is so dependent on how hard the pharmacies want to work for their patients and to put orders in. I've noticed my cvs just says "no can't get any glp1s" they don't even bother looking. Whereas my Walmart has a stocked fridge of all doses of all glp1s.

↑ 2 ↓ [Reply](#) ...



Fitz_2112b • 2mo ago •

After waiting over a week with no delivery in sight, I canceled an order for 10 mg and had my doctor send over a script for another dose of 7.5. I had that within an hour

↑ 3 ↓ [Reply](#) ...

[+](#) 3 more replies

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anything. I took a chance and decided to call 3 other Walgreens that showed I could transfer the script to in the app (I haaaaaaate calling anywhere but especially for this.). To my absolute shock and surprise the first place said they have it so I was able to fill it. I was ready to write to my dr and ask for another month of 7.5 but I got very lucky.



2



Reply

**Fun-Impression-2695** • 2mo ago •

My pharmacy said the 10 is out till mid August. I had to get 7.5 again.



2



Reply



1 more reply

**JustBrowsing2See** • 2mo ago •

Report it

<https://cdernextgenportal.fda.gov/publicportal/s/dsm-submission>



2



Reply



1 more reply

**NoPain7460** • 2mo ago •

Report it to the fda that you are experiencing a shortage



2



Reply

**allusednames** • 2mo ago •

In stock today!



2



Reply

[View more comments](#)

Exhibit 16

STATE OF FREIGHT

STATE OF FREIGHT

Port strike fallout: Blockbuster weight-loss drug supply from Wegovy to Ozempic, Mounjaro, Zepbound, caught up in East Coast trade shutdown

PUBLISHED TUE, OCT 1 2024 • 12:49 PM EDT UPDATED 15 MIN AGO



Lori Ann LaRocco
@LORIANNLAROCCO

WATCH LIVE

KEY POINTS

Customs data shows that critical medical devices and drug components for the booming new weight-loss drugs from Novo Nordisk and Eli Lilly — Ozempic, Wegovy and Mounjaro — are imported into ports where ILA union workers have gone on strike.

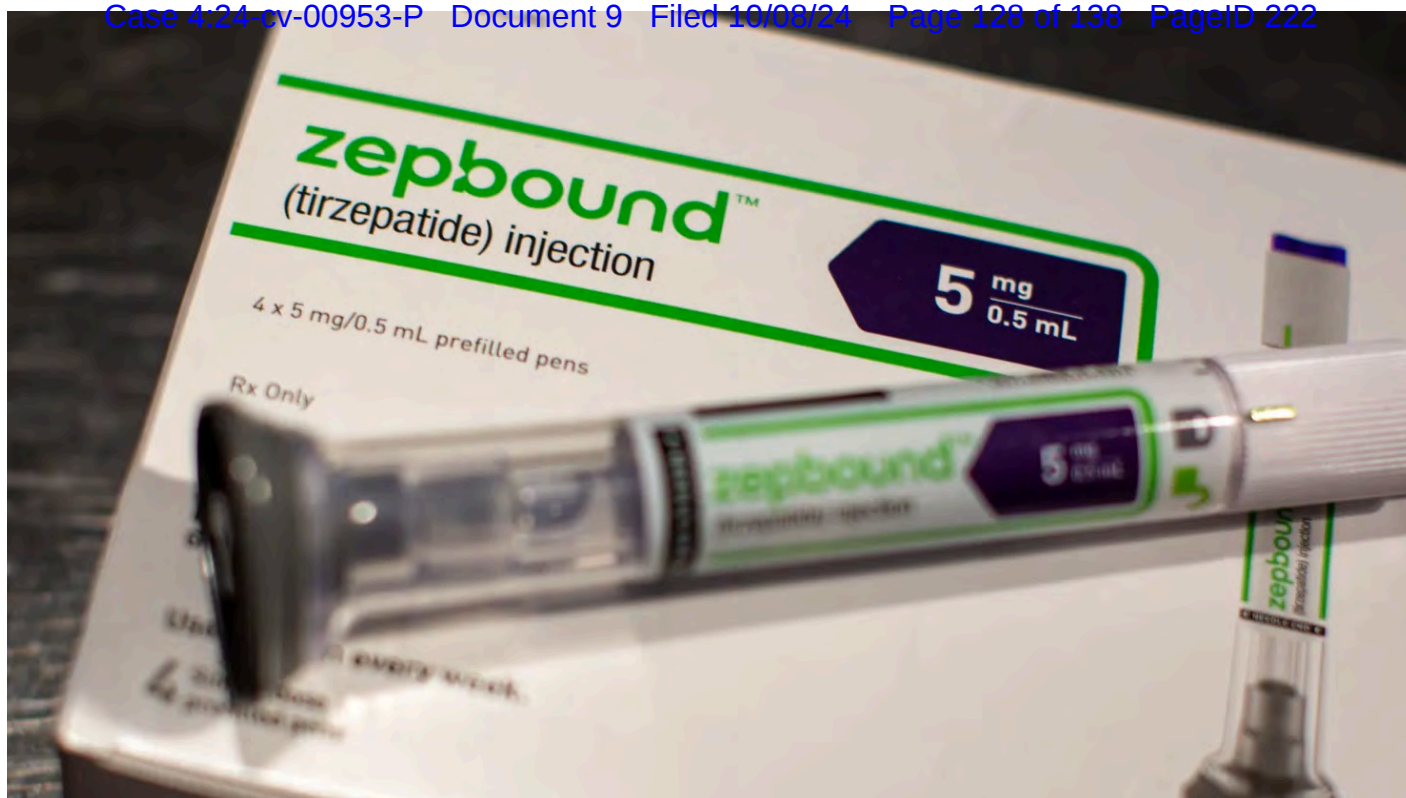
The Port of Norfolk, Virginia, in particular, one of the key East Coast ports where ILA union longshoremen walked off the job Tuesday, is critical to both companies' drug supply.

Novo Nordisk says it is redirecting trade to air freight.

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In this article

LLY **-3.07 (-0.34%)** 🌙



An Eli Lilly & Co. Zepbound injection pen, March 28, 2024.

Bloomberg | Bloomberg | Getty Images

As a [port strike stretching from New England to Texas](#) halted nearly half of all trade coming into the U.S., customs data shows that critical medical devices and drug components for the [booming, expensive weight-loss and diabetes drugs](#) from Novo Nordisk and Eli Lilly — Ozempic, Wegovy, Mounjaro and Zepbound — are among the trade casualties in the ILA union port work stoppage.

Bills of lading, the digital receipts of freight containers, show that the delivery mechanisms for insulin and weight-loss drugs rely on East Coast ports for incoming trade.

“Novo Nordisk and Eli Lilly are both heavily reliant on the Port of Norfolk,” said William George, director of research at ImportGenius, which tracks the customs data.

In the past year, [Novo Nordisk](#) has imported through Norfolk 419 twenty-foot equivalent unit, or TEU, containers worth of pharmaceuticals and injection devices that contain semaglutide, a compound in its branded weight-loss drugs, according to George. “Novo fine syringes commonly used for insulin injections come into the U.S. by ocean freight as well,” he said.

Novo Nordisk has raked in nearly \$50 billion in sales from Wegovy and Ozempic, with most of that revenue coming from the U.S., its CEO said in recent testimony before the U.S. Senate.

A Novo Nordisk spokesperson said in an email to CNBC that the company has mitigation plans in place to minimize or prevent any production disruption due to seaport strikes. “We plan to ship our

products to and from the U.S. via airfreight,” the spokesperson said.

Vials on the Wegovy line at the Novo Nordisk A/S production facilities in Hillerod, Denmark, on Friday, March 8, 2024.

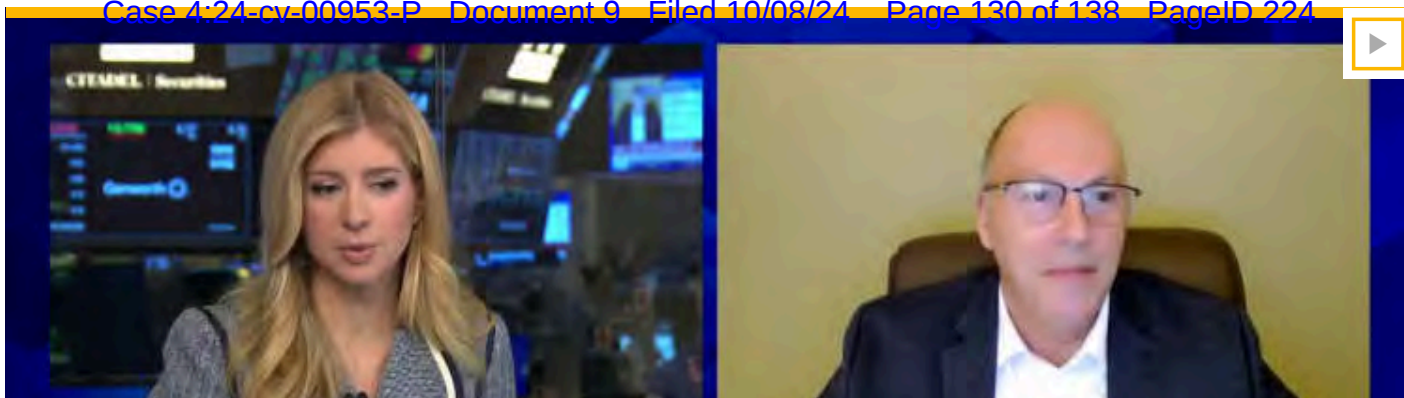
Bloomberg | Bloomberg | Getty Images

An [Eli Lilly](#) spokesperson said the company actively works to reduce exposure to risks inherent in managing a global supply chain. “We work with various partners and have multiple contingencies in place to ensure a reliable supply of our medicines,” the spokesperson said.

Dennis Monts, global chief commercial officer at PayCargo, said air sector volumes strengthened in September, peaking about two weeks ago.

“We are watching October numbers anticipating a surge of air freight for fast-moving and perishable items such as produce, seafood, medical supplies and other just-in-time inventories,” Monts said.

Noushin Shamsili, CEO and president of Nuco Logistics, which specializes in pharmaceutical imports and exports, told CNBC on Monday that the strike comes at a critical time for inventory replenishment for the drug sector. “Almost all of this industry is just on time,” said Shamsili. “Raw materials are being brought in to complete drug manufacturing.”



VIDEO 03:29

East Coast port worker strike will hit every industry, says Moody's John Donigian

Approximately 48% of the active pharmaceutical ingredients, or APIs, used in the U.S. are imported from India. Without these APIs, medications cannot be produced. APIs are also manufactured in Europe, and the U.S. points of entry for those are the East Coast ports.

Some of these APIs are critical components needed for the manufacturing of the blockbuster weight-loss drugs.

“The strike by ILA at East and Gulf coast ports could impact the importation and distribution of medications like Ozempic,” Shamsili said. “The potential effects of the strike include supply chain disruptions, increased shipping costs, inventory shortages of APIs, and production delays.”

Eli Lilly, which makes Mounjaro and [Zepbound](#), has been [expanding its production facilities](#) in the U.S., as well as in [Ireland](#), but it imports some APIs from Swiss manufacturer Corden Pharma, to produce tirzepatide for the two branded drugs. Novo Nordisk imports some of its APIs for the weight-loss drugs for Ozempic and Wegovy. The API that is used for both Ozempic and Wegovy is semaglutide.

Ports strike is a risk to medical supplies

The risk to medical supplies more broadly is being monitored by the Biden administration and state governments, such as New York.

On Monday, leaders at the Department of Health and Human Services met with trade associations, distributors, manufacturers, and other stakeholders to assess vulnerabilities and supply chain impacts, the administration said.

“Current preliminary assessments indicate immediate impacts across medicines, medical devices, and infant formula for consumers, parents, and caregivers should be limited,” the administration said in a statement. “The Administration is taking action to monitor and address potential impacts on consumers of labor disputes at East Coast and Gulf Coast ports.”

The Food and Drug Administration and the Administration for Strategic Preparedness and Response have also been in touch with trade associations, distributors, and manufacturers to limit impacts on consumers and assess vulnerabilities, the administration said.

Shamsili said the East Coast ports are also a gateway for generic medicine made in India.

Compounding the problem for the health-care industry supply chain is the ripple effects of Hurricane Helene.

Mirko Woitzik, director of intelligence solutions at Everstream Analytics, said Baxter International has a key facility in North Cove, North Carolina, that was damaged. That facility makes IV fluids that supply 60% of the U.S. market, including hospitals. The plant is also the largest U.S. supplier of intravenous and peritoneal dialysis solutions.

“The U.S. has just overcome a general shortage of IV fluids that lasted since 2014 due to production issues, recalls, and higher demand due to Covid-19,” said Woitzik. “In 2023, the U.S. FDA still listed 55 IV injection bag-related shortages.”

Gov. Kathy Hochul of New York, which is home to the largest port in the strike, said in a statement Monday night that the state is “working around the clock to ensure that our grocery stores and medical facilities have the essential products they need.”

Woitzik said that while there are other IV fluids manufacturers, including [ICU Medical](#), which has a 17% market share, and B. Braun, which has a 23% market share, they are unlikely to be able to make up the supply shortage in the short term.

“IV fluids are essential medicines used in hospitals for routine and critical care,” Woitzik said. “In the case of a shortage, elective surgeries may be impacted and patients have to stay in hospital longer due to rationing.”

He added that a similar incident occurred in 2017 when Hurricane Maria devastated multiple pharmaceutical and medical device plants in Puerto Rico, leading to shortages of IV fluids and other

patient-critical materials across the U.S. for years.

The Alliance for Chemical Distribution has said the strike will result in severe delays, reroutes, and greater uncertainties on the delivery of essential products at countless U.S. ports.

Brandon Daniels, CEO of supply chain risk management consultant Exiger, said the disaster relief agencies and the critical infrastructure providers are scrambling to triage the most important and most affected critical goods.

Some drug shipments are labeled “high-value pharmaceuticals” and “low-value pharmaceuticals.” Other shipments identify the APIs used in the U.S. to make weight loss drugs, as well as the syringes and disposable needles.

“Although 90% of containerized imports of pharmaceuticals are handled by these ports, we were able to identify that only 23 medicines in the 165 critical medicines are only manufactured through foreign sources,” said Daniels.

“High value medicines will go through air freight,” Daniels said. “We are more concerned about the existing shortages of medicines that we are already tracking and how this disruption hurts the ability to source important APIs and precursors for everything from antibiotics to pain medicines.”

Daniels said consumable products that are necessary in disaster relief such as sterile gloves and medical plastics are also processed through these ports.

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LLY -3.07 (-0.34%) 

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Biden said he won't intervene in the port strike. That decision could backfire

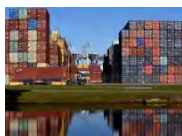


East and Gulf coast ports strike, stranding billions in trade and threatening U.S. economy

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The East and Gulf Coast ports strike could be a no-win situation for the Biden administration

Lori Ann LaRocco 11 MIN AGO



East and Gulf coast ports strike, with ILA longshoremen walking off job from New England to Texas, stranding billions in trade

[Lori Ann LaRocco](#)



VIDEO 01:33

East Coast port strike: What's at risk for the U.S. economy if ILA longshoreman walk

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Exhibit 17

From: [Jensen, Valerie E](#)
To: [Rosebush, Lee H.](#); [Bormel, Frances Gail](#)
Cc: [Wagner, Marc N.](#)
Subject: RE: [EXTERNAL] Shortage
Date: Thursday, October 3, 2024 7:33:05 AM

[External Email: Use caution when clicking on links or opening attachments.]

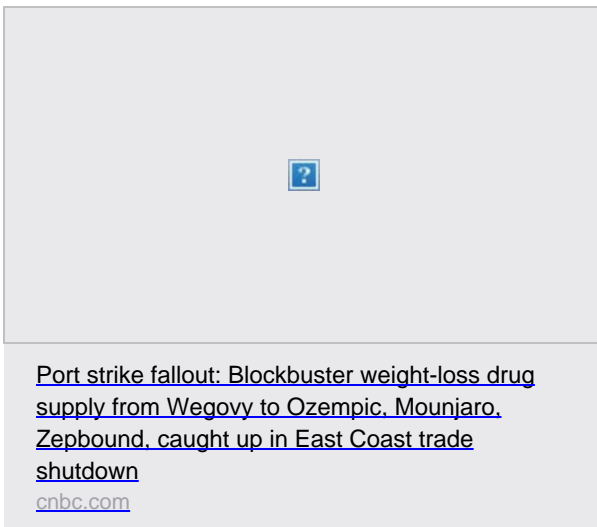
Acknowledging receipt and yes we are aware of this article. Thanks, - Val

From: Rosebush, Lee H. <lrosebush@bakerlaw.com>
Sent: Wednesday, October 2, 2024 10:11 PM
To: Bormel, Frances Gail <Frances.Bormel@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>
Cc: Wagner, Marc N. <mwagner@bakerlaw.com>
Subject: [EXTERNAL] Shortage

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Val,

With today's announcement, I wanted to make sure Lilly and Novo had reported this to you for consideration on volume and shortages



Lee